

EudraCT Number 2008-008
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Screening CRF FINAL v2: 17/11/2009

Data entered:

Participant ID:			
Participant initials:			
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SCREENING CRF

Stop

I confirm that the information c	ontained in this CRF is accurate to the best of my knowledge:	
Signed	Date	

Participant ID: Participant initials:]



BASELINE CRF

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Date of visit D D	M	M	M	`	Y	Υ	Υ	Υ	Y
<u>visdat</u>									
SECTION 1 – DEMOGRAPHICS &	DIAGNO	SIS OF	PG						
Date of birth dobdat	D	D	М	M	М	Υ	Υ	Υ	Υ
Condon									
Gender gender_nt	Male							<u></u>	
	Female							<u></u>	
Presentation of PG	Classica	l PG						<u></u>	
pgpres_n	Cribrifo	rm						(₂)	
	Peristor	mal							
	Bullous								
Unsure							☐(4)		
				T				<u></u> (5)	
Has the patient had a previous episode of PG? prev	<mark>pg_n</mark>	Yes 🗀	1)	No [] (0)		Un	known	□(8
Date of onset (approx) for this episod odatest (onset date esta	D D	M		л Y <mark>odat</mark>	Υ	Y	Tick if	f unknov	
Specialty referred from	Dermati	оюду	<u></u>						
refspec_n	Rheuma	atology						(₂₎	
	Gastroe	nterology	/						
	General	l Medicine	<u> </u>					<u></u> (3)	
								<u>(4)</u>	
	Other (p	olease spe	ecity)		rsode	<mark>et</mark>		<u></u> (5)	
Are you seeing this patient as an out-	<mark>out n</mark>	Out-pa	tient	<u>(1)</u>		In-	patient	<u></u> (2)	
patient or an in-patient?				mild disage	natient i	choice			
patient or an in-patient? Why did you choose to treat the	e.g topica	therapy no	ot working,	miiu aisease	., patient				
patient or an in-patient? Why did you choose to treat the patient with topical or systemic	e.g topica	therapy notice	ot working,	mna aisease	e, patient				
patient or an in-patient? Why did you choose to treat the	е.д горіса		ot working,	mna aisease					

Participant ID: Participant initials:				BASELINE CRF	www.stopgaptrial.co.uk	gap

		pending			
CTION 2	- MEDICATION	penang		Yes	No
the following	ent currently taking any of drugs?	Methotrexate	meth_n	□(1)	□(o)
		Azathioprine	<mark>azat_n</mark>	□ ₍₁₎	□(o)
		Leflunomide	<mark>lefl_n</mark>	□ ₍₁₎	□(o)
		Anti-TNF	<mark>atnf_n</mark>	□(1)	□(o)
		Mercaptopurine (6-MP, Puri-Nethol [®])	pure_n	□(1)	□(o)
		Tetracyclines	tetr_n	□(1)	□(o)
		Mycophenolate	<mark>myco_n</mark>	□(1)	<u></u> (0)
=	nt taken any other	If yes, please give details	of drug name(s) (dose not required):
treatment that pyoderma gar	other n	othdet1 othdet2	value	 all fields ending '_n' and have an equivaler ining the descriptive to 	nt field ending '_d'

Diagnosis		Yes	No	If the box is unshaded, please provide further
Diagnosis		163	140	details
Crohn's disease	<mark>crohn_n</mark>		□(o)	
Ulcerative colitis	<mark>ucol_n</mark>		□ ₍₀₎	
Myeloma	<mark>myel_n</mark>		□(o)	
Haematological mali	hmalig_n		□(o)	hmtype
Other malignancy – p	<mark>omalig_n</mark>		□(o)	<u>omtype</u>
Rheumatoid arthritis	<mark>rarth_n</mark>		(o)	

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CDRU

MEDH

Baseline CRF FINAL v2: 041209 Data entered:

Participant ID: Participant initials:			BA	ASELINE CRF		www.stopgapt	trial.co.uk
Other inflammatory please specify type	oarth_n		□(o)	<mark>oatype</mark>			n' contain the nume lent field ending '_d'
Monoclonal gamm	nongam_n] [(1)	□(o)		containi	ng the descriptive	e text
SECTION 4- OTHER	RELEVANT	CONDIT	IONS that ma	y involve monitoring			
Does the patient hav	e a <i>CURREN</i>	T diagnos	is of any of	the following?			
Diagnosis		Yes	No	Provide further	details if re	levant	
Diabetes	<mark>diab_n</mark>		(o)	diadet			
Mild renal impairment - clinically significant s excluded	- anything mri_n] [(1)	□(o)	mridet			
Epilepsy	epil_n		<u></u> (0)	<u>epildet</u>			
1							
SECTION 5 - PHYSIC	CAL EXAMIN	NATION					bp
Blood pressure			bpsys_t	/	br	odia_t	
(systolic / diastolic)				J /			
Weight (kg)			wtkg_t]pend	ding		
Number of ulcers on en	tire body		ulc_t				
Location of target lesion	n	Write in	free text (e.g	abdomen,	Right	Left	N/A
fields ending '_n' contain the n		shoulde	r)				
have an equivalent field ending the descriptive text.	gʻ_d' ble not		<u>lesloc</u>		<u>(1)</u>	(2)	□ ₍₈₎
elds ending '_t' contain the full					ſ	 <mark>lesIrn_n</mark>	
have a corresponding field end the numeric equivalent value.	ullig II				L	iesirii_ii	_
					г		
		Max Ion	gitudinal leng	eth (mm)		<mark>leslon_t</mark>	
0		11107 1011	0	o*** (******/		 lesper_t	
<u>nodress</u>	<mark>stoma</mark>	Max per	pendicular w	ridth (mm)	L	iespei_t	
TION 6 – INFLAI			IENT OF TH	HE TARGET LES	ON		
e tick one box onl	y Jor eacn sec	tion					
None	No erythen	าต					
							(0)
Slight	Mild pink c	olour					(1)
					<mark>ryth_n</mark>		
EudraCT Number 2008	8-008291-14		Page 5	of 120	В	Saseline CRF	FINAL v2: 041

Data entered:

Note – a value an containi

Also, all entry, ar containi

TLESION

Participant ID: Participant initials:	BASELINE CRF	www.stopgaptrial.co	Stop gap o.uk
Moderate	Moderate pink colour		
Severe	Reddish colour	☐(3)	
Very severe	Dark red or violaceous	□ ₍₄₎	
Border elevation			
None	Border is flat with ulcer and surrounding skin, no elevation	□(o)	
Slight	Slight elevation of border above ulceration and surrounding skin		
Moderate	Noticeable elevation of border above ulceration belev_n surrounding skin		
Severe	Significant elevation of border above ulceration and surrounding skin	□ ₍₃₎	
Very severe	Border rolled high above ulceration and surrounding skin	☐(4)	
Exudate			
None	Wound is dry	□(o)	
Slight	Spotting of clear fluid		
Moderate	Moderate amount of discharge, partially discolexud_n	☐ ₍₂₎	
Severe	Heavy, discoloured discharge	□ ₍₃₎	
Very severe	Copious, offensive or blood stained discharge		
SECTION 7 – TRIA	value and	fields ending '_n' contain t have an equivalent field en the descriptive text	
For patients in either	the RCT or observational study, have the following been done	? Yes	No
-	complete the 'baseline patient questions not entered	Tie	
Biopsy of the lesion This is not a requirement requested	ent, but we are interested whether one has not entered		(o)
Н	Arranged follow-up appo not entered	im	□(o)
ients in the RCT only, I	have the following been done?		
	ou would in normal care? are: full blood count, urea & electrolytes, CRP, ri		(o)

pending

seline. If unknown please

___ μmol/L *Glucose result:* ____ mmol/l

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<mark>creat_t</mark>

auto-antibodies, ANCA, serum immunoglobul

Bloods taken for creatinine & glucose

Creatinine result: ___

Please record these re

Baseline CRF FINAL v2: 041209 **Data entered:** ☐ Page 6 of 120

2 CRF.

<mark>gluc_t</mark>

 $\square_{(1)}$

 $\square_{(0)}$

bloods_n

Participant ID:					S top gap
Participant initials:			•	BASELINE CRF	www.stopgaptrial.co.uk
	- /	 		skankial auth Annal ausannan ar adı	

Urine pregnancy test (women of child-bearing potential only) and pregnancy advice		(o)
Digital images of the target lesion not entered	(₁₎	(o)
Please refer to the digital image guidance in Section 5 of this patient file and complete the Digital image log		

Please now follow the 'What to do next' sheet located behind this CRF

SECTION 8 – CRF SIGI	N-OFF									
I confirm that the information contained in this CRF is accurate to the best of my knowledge:										
Signed	 Date									

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Baseline CRF FINAL v2: 041209 Data entered:

Participant ID: Participant initials:		B	ASELINE	PATIENT Q	UESTIONI		gantrial on u	Sto	gap
						www.stop	gaptrial.co.u	IK	
Date of completion)	D	M	M compdat	M	Υ	Υ	Υ	Υ

1) We are interested in your thoughts about the **ulcer your doctor is assessing**. Please complete the table below. Feel free to ask your doctor if you do not understand how to answer these questions.

Note-fields ending '_n' contain the numeric

Colour (please tick one option	contain the descriptive text	
None	No redness	
		L) (0)
Slight	Mild pink colour	[1]
Moderate ucol_n	Moderate pink colour	□ ₍₂₎
Severe	Reddish colour	(3)
Very severe	Dark red or purple colour	(4)
Thickness of the edge of the	ne ulcer (please tick one opt	ion in this section)
None	Border is flat with ulcer and surrounding skin, no thicker	
Slight	Slight thickening of border a ulceration and surrounding	
Moderate uthick_n	Noticeable thickening of bor above ulceration and surrou skin	
Severe	Significant thickening of bor above ulceration and surrou skin	
Very severe	Border rolled high above uld and surrounding skin	ceration $\square_{\scriptscriptstyle (4)}$

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PQ

ABOUT YOUR ULCER

baseline patient CRF

<u>estdat</u>

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Participant ID:															
Participant initials:		BA	SEL	INE	P/	ΔTI	EN	T C	QUΙ	EST	ГΙС	NN	IAII	RE	



Spotting of clear fluid	(0)
	I L. I (1)
ate	
partially discoloured Heavy, discoloured discharge	(2)
	(3)
evere (4) Copious, offensive or blood staine discharge	(4)
ch pain has your pyoderma gangrenosum	□ ₍₀₎ None
u today?	□(1) Mild
pains_n	□ ₍₂₎ Moderate
	□ ₍₃₎ Severe
	LI(3) Severe
u today?	

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baseline patient CRF

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<mark>paink_n</mark>

Participant ID:						Stop
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 $\square_{\scriptscriptstyle (0)}$ No

ABOUT YOU

What is your ethnic origin? Please tick the appropriate box below.

<mark>ethnic_n</mark>

White	(1)
Black - Caribbean	(2)
Black - African	(3)
Black - Other	(4)
Asian – Indian	(5)
Asian – Pakistani	(6)
Asian – Bangladeshi	
Asian - Chinese	(8)
Asian – Other	(9)

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baseline patient CRF

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Mixed	(10)
Other	(11)
Unknown / not given	(12)

EQ5D

QUALITY OF LIFE – EQ-5D

By placing a tick in one box in each group below, pleas	e indicate which statements best describe
your own health state today.	Note – fields ending '_n' contain the numeric value, while corresponding fields ending '_d' contain the descriptive text.
Mobility	
I have no problems in walking about	Also, fields ending '_t' contain the entered text,
I have some problems in walking about	qmob_n
I am confined to bed	— (2)

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baseline patient CRF

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Se	lf-	Ca	re

I have no problems with self-care I have some problems washing or dressing myself I am unable to wash or dress myself	<mark>qcare_n</mark>	(0) (1) (2)
Usual Activities (e.g. work, study, housework, family or		
leisure activities)		
I have no problems with performing my usual activities		 (0)
I have some problems with performing my usual activit		(1)
I am unable to perform my usual activities	<mark>qact_n</mark>	(2)
Pain/Discomfort		
I have no pain or discomfort		(0)
I have moderate pain or discomfort	<mark>qpain_n</mark>	(1)
I have extreme pain or discomfort		(2)
Anxiety/Depression		
I am not anxious or depressed		(O)
I am moderately anxious or depressed	<mark>qanx_n</mark>	(1)

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baseline patient CRF

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Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



I am extremely anxious or depressed	Best
	imaginable
	100
	Ŧ
	<u>‡</u>
© 1990 EuroQol Group	#
	9 <u></u> 0
EQ-5D™ is a trade mark of the EuroQol Group	<u>‡</u>
	‡
	8 0
	<u> </u>
	‡
	7 0
	<u>‡</u>
To help people say how good or bad a health state is, we	‡
have drawn a scale (rather like a thermometer) on which	6 ≠ 0
the best state you can imagine is marked 100 and the	<u> </u>
worst state you can imagine is marked 0.	Ŧ
	5 <u>+</u> 0
We would like you to indicate on this scale how good or	<u>‡</u>
bad your own health is today, in your opinion. Please do	‡
	4 10
	<u>‡</u>
	‡
	3 0
	<u>‡</u>
	‡
	2 0
	<u> </u>
	‡
	1 0
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Worst

imaginable

Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



hstate_t

Your own health state

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baseline patient CRF

Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



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baseline patient CRF

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Participant initials:		ВА	SEL	INE	PATIENT QUESTIONNAIRE	gap
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rmatology Life Quality Index

Score	
	dscore

The aim of this questionnaire is to measure how much your skin problem has affected your life over the last week. Please tick one box for each question.

Over the last week, how itchy , sore , painful or stinging has	Very much	□ ₍₃₎	
your skin been? ditch_n	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□(o)	
Over the last week, how embarrassed or self conscious have	Very much	□ ₍₃₎	
you been because of your skin? demb_n	A lot	□ ₍₂₎	
	A little	 (1)	
	Not at all	□ ₍₀₎	
Over the last week, how much has your skin interfered with	Very much	□ ₍₃₎	
you going shopping or looking after your home or garden? dshop_n	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much has your skin influenced the	Very much	□ ₍₃₎	
clothes you wear? dclothes_n	A lot	□ ₍₂₎	
	A little	 (1)	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much has your skin affected any	Very much	□ ₍₃₎	
social or leisure activities? dsocial_n	A lot	□ ₍₂₎	

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Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



	A little	 (1)	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much has your skin made it	Very much	□ ₍₃₎	
difficult for you to do any sport ? dsport_n	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, has your skin prevented yo dwork n	yes	□ ₍₁₎	
working or studying?	no	□ ₍₀₎	Not relevant □(8)
If "No", over the last week how much has your skin been a	A lot	□ ₍₂₎	
problem at work or studying? dwmuch_n	A little	 (1)	
	Not at all	□ ₍₀₎	
Over the last week, how much has your skin created	Very much	□ ₍₃₎	
problems with your partner or any of your close friends or relatives?	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much has your skin caused any	Very much	□ ₍₃₎	
sexual difficulties? dsex_n	A lot	□ ₍₂₎	
	A little	 (1)	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much of a problem has the	Very much	□(3)	
treatment for your skin been, for example by making your home messy, or by taking up time? dtreat_n	A lot	□ ₍₂₎	
	A little	 (1)	
		□ ₍₀₎	

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baseline patient CRF

	Participant ID: Participant initials:		BASELINE	PATIENT QUESTION	NNAIRE www.stopgap	trial.co.uk	Stop gap
					Not at all		Not relevant □(8)
© _{AY}	Finlay, GK Khan, April 1992	, This must not	be copied witho	ut the permission of the		orresponding	ontain the numeric fields ending '_d' t

NOT ENTERED

YOUR CONTACT DETAILS

Please complete your contact details below.

We would like these details so that members of the *research team at the co-ordinating centre* can get in touch with you during the period of the research. We will not pass these details on to anyone other than members of the study team without your permission, and will hold this information on a password protected database.

Title						
	Mr	Mrs	Miss	Ms	Dr	Other
(Please circle as appropriate)						
Forename						
Surname						

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Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



Address	
Postcode	
Telephone number (home)	
Telephone number (mobile)	
Email address (if available)	
What is the best time to contact you?	

GP CONTACT DETAILS (if known)

We will contact your GP and let him/her know that you are taking part in this study.

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baseline patient CRF

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					٦									
Participant ID:					╛									
Participant initials:		B/	SEL	INF	D/	۱TI	FNI-	тΛ	HE	STI	NI	NVIE) F	
Faiticipant initials.		DF	JLL	IIVL	F <i>F</i>	1111	LIV	ı Q	OL.) I I	JIVI	VAII.	\L	



Name of GP	
A d due a a	
Address	
Postcode	
. 0000000	
Telephone number	

Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



Thank you for completing these questions.

Please return these forms to your doctor (or if you have been sent them by post, please return them to the research team in the reply paid envelope provided).

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

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Participant ID:						
Participant initials:		BA	ASEL	INE	PATIENT QUESTIONNAIRE	





STOP GAP RESEARCH STUDY

PATIENT DIARY 1 (0-6 WEEKS)

Observational Study patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

Participant ID:						Stop
Participant initials:		ВА	SELI	NE	PATIENT QUESTIONNAIRE	gap
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- Whether you are still using dressings for your ulcer

How much pain your ulcer has caused you

This diary should be completed **every day** for 6 weeks.

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8230489 or 0115 8230486**

Your local STOP GAP study doctor is:

THIS PAGE IS NOT ENTERED

Name	
Hospital name	
Telephone number	

	1	1				1
Participant ID:						
Participant initials:			B/	\CEI	INE	PATIENT QUESTIONNAIRE
raiticipant initials.			DF	JUL	IIVL	PATILINI QULSTIONNAINL



The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Julie Barnes
Address	Nottingham Clinical Trials Unit B39, Medical School Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8230489 / 0115 8230486
Email address	stopgap@nottingham.ac.uk





If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.

Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



It is important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

The ulcer being studied is:

Participant ID: Participant initials: BASELINE PATIENT QUE	STIONNAIRE	Stop
PDIARY notdone 1: week commencing date:	commdat	Week number is denoted by field 'recno'
The date I started using cream/ointment was:		tabdat

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your	□ None	□ None	□ None	□ None	□ None	□ None	□ None
pyoderma gangrenosum (PG) given you today?	Mild pg_mon	□ Mild pg_tues	Mild pg_wed	☐ Mild pg_thur	☐ Mild pg_fri	Mild pg_sat	Mild pg_sun
	□ Severe	□ Severe	□ Severe	□ Severe	□ Severe	□ Severe	□ Severe
	☐ Extreme	□ Extreme	□ Extreme	□ Extreme	□ Extreme	□ Extreme	□ Extreme
Have you taken any painkillers for your PG?	□ pn_mon □ No	pn_tues No	□ pn_wed □ No	□ pn_thur □ No	□ pn_fri □ No	□ pn_sat □ No	□ pn_sun □ No
Have you been using dressings?	drs_mon	drs_tues No	drs_wed	drs_thur	drs_fri	drs_sat	drs_sun No
!!! IMPORTANTPLEA	ASE REMEMBER	TO CONTACT TI	HE CO-ORDINATIN	NG CENTRE AS	SOON AS YOU S	TOP USING DRI	ESSINGS!!!!

Participant ID:						
Participant initials:			B/	SEL	INE	PATIENT QUESTIONNAIRE
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WEEK 2: week commencing date: _____

	ı	Monday	1	Tuesday	V	Vednesday	Т	hursday	Friday	S	aturday	Sunday
How much pain has your		None		None		None		None	None		None	None
pyoderma gangrenosum (PG) given you today?		Mild		Mild		Mild		Mild	Mild		Mild	Mild
		Moderate		Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
		Severe		Severe		Severe		Severe	Severe		Severe	Severe
		Extreme		Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any		Yes		Yes		Yes		Yes	Yes		Yes	Yes
painkillers for your PG?		No		No		No		No	No		No	No
Have you been using		Yes		Yes		Yes		Yes	Yes		Yes	Yes
dressings?		No		No		No		No	No		No	No

Participant ID:						
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIRI
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!!! IMPORTANT	PLEASE REMEMBER 1	O CONTACT THE CO	O-ORDINATING CENTRE	AS SOON AS YOU ST	OP USING DRESSINGS!!!!
21 11 01(17/11(17)		0 001117101 1112 0	O OKDINATING CENTRAL	. 7.5 50011 7.5 100 5	01 001110 DIVEDOTITOD

WEEK 3: week commencing date: _____

	Monday	٦	Tuesday	٧	Vednesday	Т	hursday	Friday	S	Saturday	Sunday
How much pain has your	None		None		None		None	None		None	None
pyoderma gangrenosum (PG)	Mild		Mild		Mild		Mild	Mild		Mild	Mild
given you today ?	Moderate		Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
	Severe		Severe		Severe		Severe	Severe		Severe	Severe
	Extreme		Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any painkillers for your PG?	Yes		Yes		Yes		Yes	Yes		Yes	Yes
pankiners for your FG:	No		No		No		No	No		No	No

Participant ID: Participant initials: BASELINE PATIENT QUESTIONNAIRE www.stopgaptrial.co.uk										
Have you been using dressings?	☐ Yes	□ Yes	□ Yes	☐ Yes	☐ Yes ☐ No	☐ Yes ☐ No	□ Yes			
!!! IMPORTANTPLEA	SE REMEMBER	TO CONTACT TI	HE CO-ORDINATIN	NG CENTRE AS S	SOON AS YOU S	TOP USING DRI	ESSINGS!!!!			
WEEK 4: week commencing date: Monday Tuesday Wednesday Thursday Friday Saturday Sunday										
	-	-	_		-		-			
How much pain has your pyoderma	□ None	□ None	□ None □ Mild	□ None □ Mild	□ None □ Mild	□ None □ Mild	□ None			

Moderate

Severe

Extreme

☐ Yes

EudraCT No	2008-008	3291-14

given you today?

Have you taken any

Moderate

Severe

☐ Extreme

☐ Yes

Moderate

Severe

Extreme

☐ Yes

☐ Yes

Moderate

Severe

Extreme

Moderate

Severe

Extreme

☐ Yes

Moderate

Severe

☐ Extreme

☐ Yes

Moderate

Severe

☐ Extreme

☐ Yes

Participant ID: Participant initials: www.stopgaptrial.co.uk		INE PATIENT QUEST	ΓΙΟΝΝΑΙRE	Stop			
painkillers for your PG?	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you been using dressings?	☐ Yes	☐ Yes	□ Yes	□ Yes	☐ Yes	☐ Yes	□ Yes
	□ No	□ No	□ No	□ No	□ No	□ No	□ No
!!! IMPORTANTPLEA	SE REMEMBER	TO CONTACT TI	HE CO-ORDINATIN	IG CENTRE AS S	SOON AS YOU S	TOP USING DRE	ESSINGS!!!!
WEEK 5: week comr	nencing date:						
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your pyoderma	□ None	□ None	□ None	□ None	□ None	□ None	□ None
gangrenosum (PG) given you today?	☐ Mild	☐ Mild	☐ Mild	☐ Mild	☐ Mild	☐ Mild	☐ Mild

Participant ID:					
Participant initials:			BA	SEL	INE PATIENT QUESTIONNAIRE
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		Moderate		Moderate		Moderate		Moderate		Moderate		Moderate		Moderate
		Severe		Severe		Severe		Severe		Severe		Severe		Severe
		Extreme		Extreme		Extreme		Extreme		Extreme		Extreme		Extreme
Have you taken any		Yes		Yes		Yes		Yes		Yes		Yes		Yes
painkillers for your PG?		No		No		No		No		No		No		No
Have you been using		Yes		Yes		Yes		Yes		Yes		Yes		Yes
dressings?		No		No		No		No		No		No		No
!!! IMPORTANTPLEA	SE F	REMEMBER	то с	CONTACT TH	HE C	O-ORDINATIN	IG C	ENTRE AS S	600I	N AS YOU S	тор	USING DRI	ESSI	NGS!!!!
WEEK 6: week commencing date:														

Wednesday

Tuesday

Monday

Thursday

Friday

Saturday

Sunday

Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



How much pain has your		None		None		None		None		None		None		None
pyoderma gangrenosum (PG)		Mild		Mild		Mild		Mild		Mild		Mild		Mild
given you today ?		Moderate		Moderate		Moderate		Moderate		Moderate		Moderate		Moderate
		Severe		Severe		Severe		Severe		Severe		Severe		Severe
		Extreme		Extreme		Extreme		Extreme		Extreme		Extreme		Extreme
Have you taken any		Yes		Yes		Yes		Yes		Yes		Yes		Yes
painkillers for your PG?		No		No		No		No		No		No		No
Have you been using		Yes		Yes		Yes		Yes		Yes		Yes		Yes
dressings?		No		No		No		No		No		No		No
!!! IMPORTANTPLEA	SE F	REMEMBER	то (CONTACT TI	HE C	O-ORDINATIN	IG C	ENTRE AS S	600I	N AS YOU S	тор	USING DRI	ESSI	NGS!!!!

Participant ID:						
Participant initials:			B/	ASEL	INE	PATIENT QUESTIONNAIR
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WEEK 7: week commencing date:

	Monday	Tuesday	V	Vednesday	Т	hursday	Friday	S	aturday	Sunday
How much pain has your pyoderma	None	None		None		None	None		None	None
gangrenosum (PG)	Mild	Mild		Mild		Mild	Mild		Mild	Mild
given you today ?	Moderate	Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
	Severe	Severe		Severe		Severe	Severe		Severe	Severe
	Extreme	Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any painkillers for your PG?	Yes	Yes		Yes		Yes	Yes		Yes	Yes
panikiners for your FG:	No	No		No		No	No		No	No
Have you been using dressings?	Yes	Yes		Yes		Yes	Yes		Yes	Yes
uressings:	No	No		No		No	No		No	No

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:						
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIRE
www.stopgaptrial.co.	uk					



WEEK 8: week commencing date: _____

	Monday	1	Гuesday	V	Vednesday	Т	hursday	Friday	S	aturday	Sunday
How much pain has your pyoderma	None		None		None		None	None		None	None
gangrenosum (PG)	Mild		Mild		Mild		Mild	Mild		Mild	Mild
given you today ?	Moderate		Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
	Severe		Severe		Severe		Severe	Severe		Severe	Severe
	Extreme		Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any painkillers for your PG?	Yes		Yes		Yes		Yes	Yes		Yes	Yes
pariminers for your re-	No		No		No		No	No		No	No
Have you been using dressings?	Yes		Yes		Yes		Yes	Yes		Yes	Yes
a. 333go.	No		No		No		No	No		No	No

Participant ID:						
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIRE
www.stopgaptrial.co.	uk					



!! IMPORTANTPLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!	

Participant ID: Participant initials: BASELINE PATIENT QUESTIONNAIF www.stopgap	
DIARYEND	otilal.co.uk
Since you started value notdone	have you taken your tablets
Every day	
Most days tabtake	
Some days	
Never	
If you would like to add any comments, please do so he	ere:

comm1

<mark>comm3</mark>

comm2

Participant ID:					
Participant initials:		BA	ASEL	INE	PATIENT QUESTIONNAIRE





STOP GAP RESEARCH STUDY

PATIENT DIARY 1 (0-6 WEEKS)

RCT patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

Participant ID:					
Participant initials:		BASELINE I		INE	PATIENT QUESTIONNAIRE
					www.stopgaptrial.co.uk



- How much pain your ulcer has caused you
- · Whether your pyoderma gangrenosum has affected your daily activities
- Whether you are still using dressings for your ulcer
- Any illnesses you have experienced
- Any visits you have made to your GP or hospital

This diary should be completed **every day** for 6 weeks.

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8230489 or 0115 8230486**



Your local STOP GAP study doctor is:

Name	
Hospital name	
Telephone number	

Participant ID:					
Participant initials:		BA	SEL	INE	PATIENT QUESTIONNAIRE



The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Julie Barnes
Address	Nottingham Clinical Trials Unit Office B39, Medical School Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8230489 / 0115 8230486
Email address	stopgap@nottingham.ac.uk

Participant ID:					
Participant initials:		ВА	SEL	INE	PATIENT QUESTIONNAIRE



If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.



It is important, however, that you **do not** stop taking the tablets suddenly as this can be very dangerous. Please talk to your doctor first who will be able to advise you what to do.



It is also important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

NOT ENTERED

The ulcer being studied is:

Participant ID: Participant initials: BASELINE PATIENT	T QUESTIONNAIRE	Stop
PDIARY notdone vee ncing date:	<mark>commdat</mark>	Note: Week number is denoted by the value in the field 'recno'
The date I started taking tablets on:	<mark>tabdat</mark>	

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your pyoderma	□ None	□ None	□ None	□ None	□ None	□ None	□ None
gangrenosum (PG) given you today?	☐ Mild	☐ Mild	☐ Mild	☐ Mild	☐ Mild	☐ Mild	☐ Mild
	pg_mon	pg_tues	pg_wed	pg_thur	pg_fri	pg_sat	pg_sun
	☐ Extreme	□ Extreme	□ Extreme	☐ Extreme	□ Extreme	□ Extreme	□ Extreme
Have you taken any painkillers?	pn_mon	pn_tues	pn_wed	pn_thur	pn_fri	pn_sat	pn_sun
Have you been able to work/do usual activities?	□ Yes	□ Ye	sumwk_t – total	of all 'yes' answers	for week	Yes	□ Yes
	□ No	□ Nd				No No	□ No
Have you been using dressings?	drs_mon	drs_tues	drs_wed	drs_thur	drs_fri	drs_sat	drs_sun

EudraCT No 2008-008291-14

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Patient Diary 1 (0-6 weeks) RCT_v1_270309

Participant ID:						
Participant initials:			B/	ASEL	INE	PATIENT QUESTIONNAIRI
www.stopgaptrial.co.	uk					



Have you had any health problems? Not entered Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication gps t – total of all ticked answers for week **GP Surgery** GP Home \Box gph t – total of all ticked answers for week П Practice Nurse pn t – total of all ticked answers for week dn t – total of all ticked answers for week District Nurse П П opa t – total of all ticked answers for week **Out Patient Appointment** In Patient ip t – total of all ticked answers for week Other, please specify: П П oth_t – total of all ticked answers for week othdet1 othdet2 othdet3 Note: All fields that end with '_t' contain the actual text input. They all have a corresponding field ending '_n' which

WEEK 2: week comn EudraCT No 2008-008 contain the numeric value if appropriate.

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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Monday Tuesday Wednesday **Thursday** Friday Saturday Sunday How much pain has your None None None None None None None pyoderma Mild Mild Mild Mild Mild Mild Mild gangrenosum (PG) given you today? Moderate Moderate Moderate Moderate Moderate Moderate Moderate Severe Severe Severe Severe Severe Severe Severe

Participant ID:									
Participant initials:				BA	ASEL	INE	PATIENT QUESTIONNAIRE		
www.stopgaptrial.co.uk									



Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication **GP Surgery** П П \Box GP Home Practice Nurse District Nurse \Box П П П П Out Patient Appointment In Patient Other, please specify:

Participant ID:						
Participant initials:			BA	SEL	INE	PATIENT QUESTIONNAIRI
www.stongantrial.co	uk					



WEEK 3: week commencing date: _____

	Monday	-	Tuesday	V	Vednesday	hursday	Friday	S	aturday	Sunday		
	, ,			_		_	,	, , ,				Juliuu,
How much pain has your pyoderma	None		None		None		None	None		None		None
gangrenosum (PG)	Mild		Mild		Mild		Mild	Mild		Mild		Mild
given you today ?	Moderate		Moderate		Moderate		Moderate	Moderate		Moderate		Moderate
	Severe		Severe		Severe		Severe	Severe		Severe		Severe
	Extreme		Extreme		Extreme		Extreme	Extreme		Extreme		Extreme
Have you taken any	Yes		Yes		Yes		Yes	Yes		Yes		Yes
painkillers?	No		No		No		No	No		No		No
Have you been able to	Yes		Yes		Yes		Yes	Yes		Yes		Yes
work/do usual activities?	No		No		No		No	No		No		No
Have you been using dressings?	Yes		Yes		Yes		Yes	Yes		Yes		Yes
uressifigs:	No		No		No		No	No		No		No
Have you had any health												

Participant ID:						
Participant initials:			BA	ASEL	INE	- PATIENT QUESTIONNAIRE
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problems? Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication GP Surgery GP Home Practice Nurse District Nurse Out Patient Appointment In Patient Other, please specify:

WEEK 4: week commencing (date:				
EudraCT No 2008-008291-14	Page 48 of 120	Patient Diary 1 (0-	-6 weeks) RCT_	_v1_	27030

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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Monday Tuesday Wednesday **Thursday** Friday Saturday Sunday How much pain has your None None None None None None None pyoderma Mild Mild Mild Mild Mild Mild Mild gangrenosum (PG) given you today? Moderate Moderate Moderate Moderate Moderate Moderate Moderate Severe Severe Severe Severe Severe Severe Severe Extreme Extreme Extreme Extreme Extreme Extreme Extreme Have you taken any Yes Yes Yes Yes Yes Yes Yes painkillers? No No No No No No No Have you been able to Yes Yes Yes Yes Yes ☐ Yes Yes work/do usual activities? No No No No No No No Have you been using Yes Yes Yes Yes Yes Yes Yes

Nο

Nο

dressings?

problems?

Have you had any health

Nο

Nο

Nο

Nο

Nο

Participant ID:							
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIR	RE
www.stopgaptrial.co.	uk						



Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication GP Surgery П GP Home Practice Nurse District Nurse П П П Out Patient Appointment In Patient Other, please specify:

WEEK 5: week commencing of	date:		
EudraCT No 2008-008291-14	Page 50 of 120	Patient Diary 1 (0-6 weeks) RCT_v1_270	30

Participant ID:
Participant initials:

BASELINE PATIENT QUESTIONNAIRE



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	Monday	•	Tuesday	V	Vednesday	Т	hursday	Friday	S	aturday	Sunday
How much pain has your pyoderma	None		None		None		None	None		None	None
gangrenosum (PG) given you today?	Mild		Mild		Mild		Mild	Mild		Mild	Mild
given you today :	Moderate		Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
	Severe		Severe		Severe		Severe	Severe		Severe	Severe
	Extreme		Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any painkillers?	Yes		Yes		Yes		Yes	Yes		Yes	Yes
	No		No		No		No	No		No	No
Have you been able to work/do usual activities?	Yes		Yes		Yes		Yes	Yes		Yes	Yes
·	No		No		No		No	No		No	No
Have you been using dressings?	Yes		Yes		Yes		Yes	Yes		Yes	Yes
_	No		No		No		No	No		No	No
Have you had any health problems?											

Participant ID:						
Participant initials:			BA	ASEL	INE	- PATIENT QUESTIONNAIRE
www.stopgaptrial.co.	uk					



Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication GP Surgery П П GP Home Practice Nurse District Nurse П П П Out Patient Appointment In Patient Other, please specify:

WEEK 6: week commencing	date:		
EudraCT No 2008-008291-14	Page 52 of 120	Patient Diary 1 (0-6 weeks) RCT_v1_270	309

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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Monday Tuesday Wednesday **Thursday** Friday Saturday Sunday How much pain has your None None None None None None None pyoderma Mild Mild Mild Mild Mild Mild Mild gangrenosum (PG) given you today? Moderate Moderate Moderate Moderate Moderate Moderate Moderate Severe Severe Severe Severe Severe Severe Severe Extreme Extreme Extreme Extreme Extreme Extreme Extreme Have you taken any Yes Yes Yes Yes Yes Yes Yes painkillers? No No No No No No No Have you been able to Yes Yes Yes Yes Yes ☐ Yes Yes work/do usual activities? No No No No No No No Have you been using Yes Yes Yes Yes Yes Yes Yes dressings? Nο Nο Nο Nο Nο Nο Nο Have you had any health problems?

Participant ID:						
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIRE
www.stopgaptrial.co.	uk					



Please specify							
!!! IMPORTANTPLEA	SF REMEMBER	TO CONTACT TH	HE CO-ORDINATIN	IG CENTRE AS S	SOON AS YOU S	TOP USING DRI	SSINGSIIII
I'll OKIAKIIIII EEA	ISE REPIEITISER	ro contract ii	ie do okbinatio	to certific AS c	OCH AS 100 S	TOT OSTITO DIC	
Please tick if you have a	ccessed any of	the following b	ecause of vour pv	oderma gangre	nosum or beca	use of possible	side-effects of
the medication	,		, , , , , , , , , , , , , , , , , , ,				
	1	T	T	T	T	T	
GP Surgery							
GP Home							
Practice Nurse							
District Nurse							
Out Patient Appointment							
			_	_			
In Patient							
Other, please specify:							

WEEK 7: week commencing date:	

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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Yes

No

Yes

Nο



Yes

No

Yes

Nο

☐ Yes

No

Yes

Nο

Monday Tuesday Wednesday **Thursday** Friday Saturday Sunday How much pain has your None None None None None None None pyoderma Mild Mild Mild Mild Mild Mild Mild gangrenosum (PG) given you today? Moderate Moderate Moderate Moderate Moderate Moderate Moderate Severe Severe Severe Severe Severe Severe Severe Extreme Extreme Extreme Extreme Extreme Extreme Extreme Have you taken any Yes Yes Yes Yes Yes Yes Yes painkillers? No No No No No No No

Have you been able to

Have you been using

dressings?

problems?

work/do usual activities?

Have you had any health

Yes

No

Yes

Nο

Yes

No

Yes

Nο

Yes

No

Yes

Nο

Yes

No

Yes

Nο

Participant ID:						
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIRE
www.stopgaptrial.co.	uk					



Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication GP Surgery GP Home Practice Nurse District Nurse П П П Out Patient Appointment In Patient Other, please specify:

WEEK 8: week commencing (date:			
EudraCT No 2008-008291-14	Page 56 of 120	Patient Diary 1 (0-6 w	eeks) RCT_v1	27030

Participant ID:

Participant initials:

BASELINE PATIENT QUESTIONNAIRE

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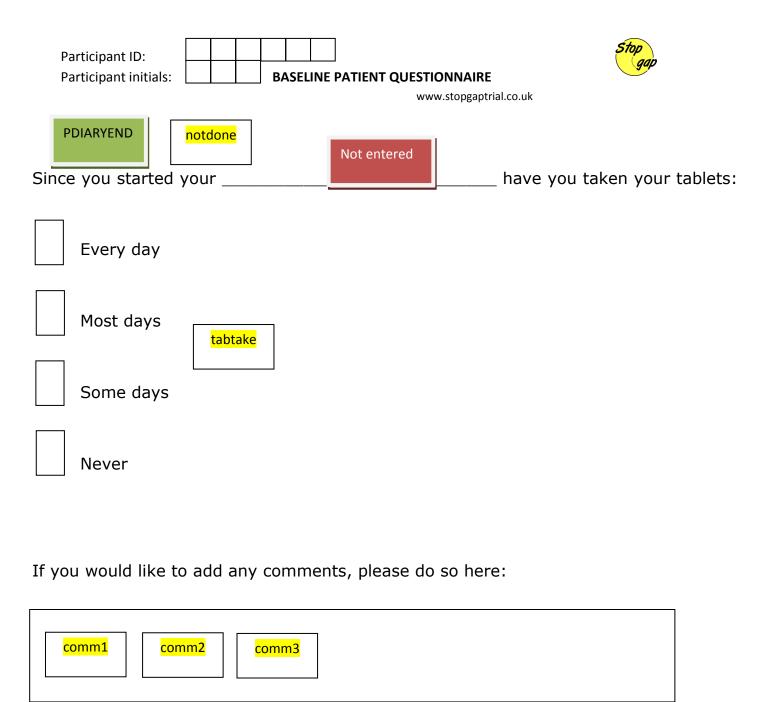


Monday Tuesday Wednesday **Thursday** Friday Saturday Sunday How much pain has your None None None None None None None pyoderma Mild Mild Mild Mild Mild Mild Mild gangrenosum (PG) given you today? Moderate Moderate Moderate Moderate Moderate Moderate Moderate Severe Severe Severe Severe Severe Severe Severe Extreme Extreme Extreme Extreme Extreme Extreme Extreme Have you taken any Yes Yes Yes Yes Yes Yes Yes painkillers? No No No No No No No Have you been able to Yes Yes Yes Yes Yes ☐ Yes Yes work/do usual activities? No No No No No No No Have you been using Yes Yes Yes Yes Yes Yes Yes dressings? Nο Nο Nο Nο Nο Nο Nο Have you had any health problems?

Participant ID:						
Participant initials:			BA	ASEL	INE	PATIENT QUESTIONNAIRE
www.stopgaptrial.co.	uk					



Please specify !!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!! Please tick if you have accessed any of the following because of your pyoderma gangrenosum or because of possible side-effects of the medication **GP Surgery** П П \Box GP Home Practice Nurse District Nurse \Box П П П П Out Patient Appointment In Patient Other, please specify:



Please now record any prescriptions you have been given for your pyoderma gangrenosum (e.g tablets, creams, dressings, bandages etc).

Participant ID:					
Participant initials:		BA	ASEL	INE	PATIENT QUESTIONNAIRE



Prescription type / name of medicine	Dose / number of items (if applicable)
pres1	pres1dos
pres2	pres2dos
pres3	pres3dos
pres4	pres4dos
pres5	pres5dos
pres6	pres6dos

	Participant ID: Participant initials:		WEEK		ww.stopgaptrial.co.uk
VISITS					
	Date of visit D	M M visda	et Y	Y	Y
PHYEXA	SECTION 1 – PHYSICAL EXAMINAT	corre		contain the actual text i	input; they all have e corresponding numeric
	Measurement of target lesion	Max longitudinal length	(mm)	leslon_t	
		Max perpendicular width	n (mm)	lesper_t	
CDRU	G pend	ding			
	SECTION 2 – MEDICATION			Yes	No
	Is Is the patient currently taking any of the following drugs?	Methotrexate	meth_n		□(o)
		Azathioprine	<mark>azat_n</mark>		□(o)
		Leflunomide	<mark>lefl_n</mark>	☐(1)	□(o)
		Anti-TNF	atnf_n		□(o)
		Mercaptopurine (6-MP, Puri-Nethol [®])	<mark>pure_n</mark>	☐(1)	□(o)
		Tetracyclines	tetr_n		□(o)
		Mycophenolate	myco_n		□(o)
	Has the patient taken any other treatment that could influence	If yes, please give deta	ails of drug name	(s) (dose not require	ed):

othdet1

othdet2

RESULTS pending confirm

SECTION 3 – RESULTS

pyoderma gangrenosum?

Yes □(1) No □(2)

EudraCT Number 2008-008291-14 Page 61 of 120 PLEASE NOTE THIS IS A SOURCE DOCUMENT

other_n

week 2 CRF FINAL v2.5 050310 Data entered:

Participant ID:				
Participant initials:				ı

WEEK 2 CRF



Was a bio	psy of the target lesion	Yes $\square_{(1)}$		No □(0) go	go to Section 4			
If yes, doe lesion is N	s the biopsy suggest the OT PG?	Yes □(1) Please exclude this	s narticinant	No □(0)				
		immediately and of status CRF locate the patient file	complete a change					
· ·	not previously record the	Creatinine (µmol/L	-)	creat_t				
	& glucose result in the RF, please do so here	Glucose (mmol/l)		gluc_t				
SECTION	pendi 4 – INVESTIGATOR GLO	OBAL ASSESSME	Note: All fields ending '_t' corresponding fields endin value if appropriate		ext input; they all have n the corresponding numeric			
Since the E	BASELINE visit, has the targe	— t lesion improved?		lesimp_n]			
Grade								
Grade				<u> </u>	Tick below			
0	Completely clear: excep	ot for possible residua	l hyperpigmentation		Tick below			
	Completely clear: excep Almost clear: very signi erythema and/or very s	ficant clearance (abou			(o)			
0	Almost clear: very signi	ficant clearance (abous small ulceration significant improveme emaining ulcers, altho	ut 90%); however, pat ent (about 75%); how ough have decreased	cchy remnants of	f dusky $\square_{(1)}$			
0	Almost clear: very signi erythema and/or very signi erythema and/or very signi Marked improvement: disease remaining (i.e. r erythema and/or barely Moderate improvement	ficant clearance (about small ulceration significant improvement remaining ulcers, although y perceptible border eats it: intermediate between	ent (about 75%); however, pat ent (about 75%); how ough have decreased elevation) een slight and marked	ever, a small am in size, minimal i; representing a	$\square_{(0)}$ If dusky $\square_{(1)}$ Injury $\square_{(2)}$ Injury $\square_{(2)}$ Injury $\square_{(3)}$			
0 1 2	Almost clear: very signi erythema and/or very signi erythema and/or very signi Marked improvement: disease remaining (i.e. r erythema and/or barely Moderate improvement 50% improvement Slight improvement: so remaining (i.e. remaining elevation)	ficant clearance (about small ulceration significant improvement of the province of the provin	ent (about 75%); however, patent (about 75%); however, patent (about 75%); however, sinor decrease in size, e	ever, a small am in size, minimal i; representing a gnificant disease	f dusky $\square_{(1)}$ fount of $\square_{(2)}$ bout $\square_{(3)}$ e $\square_{(4)}$			
0 1 2 3	Almost clear: very signi erythema and/or very signi erythema and/or very signi erythema and/or very signi disease remaining (i.e. rerythema and/or barely Moderate improvement 50% improvement Slight improvement: so remaining (i.e. remaining elevation)	ficant clearance (about small ulceration significant improvement of the province of the provin	ent (about 75%); however, patent (about 75%); however, patent (about 75%); however, sinor decrease in size, econtain the numeric entry;	ever, a small am in size, minimal i; representing a gnificant disease rythema or borce; they have a corres	f dusky $\square_{(1)}$ fount of $\square_{(2)}$ bout $\square_{(3)}$ e $\square_{(4)}$			
0 1 2 3	Almost clear: very signi erythema and/or very signi erythema and/or very signi erythema and/or very signi disease remaining (i.e. rerythema and/or barely Moderate improvement 50% improvement Slight improvement: so remaining (i.e. remaining elevation)	ficant clearance (about small ulceration significant improvement emaining ulcers, although perceptible border eat: intermediate between the improvement (about the improvement (about the improvement) in the significant in t	ent (about 75%); however, patent (about 75%); however, patent (about 75%); however, sinor decrease in size, econtain the numeric entry;	ever, a small am in size, minimal i; representing a gnificant disease rythema or borce; they have a corres	f dusky $\square_{(1)}$ fount of $\square_{(2)}$ bout $\square_{(3)}$ e $\square_{(4)}$			
0 1 2 3 4	Almost clear: very signi erythema and/or very signi erythema and/or very signi Marked improvement: disease remaining (i.e. rerythema and/or barely Moderate improvement 50% improvement Slight improvement: so remaining (i.e. remaining elevation) No change from b	ficant clearance (about small ulceration significant improvement emaining ulcers, although perceptible border eat: intermediate between the improvement (about the improvement (about the improvement) in the significant in t	ent (about 75%); however, patent (about 75%); however, patent (about 75%); however, sinor decrease in size, econtain the numeric entry;	ever, a small am in size, minimal i; representing a gnificant disease rythema or borce; they have a corres	f dusky $\square_{(1)}$ fount of $\square_{(2)}$ bout $\square_{(3)}$ e $\square_{(4)}$ ponding $\square_{(5)}$			
0 1 2 3 4 5 6 ON SECTION	Almost clear: very signi erythema and/or very signi erythema and/or very signi disease remaining (i.e. rerythema and/or barely Moderate improvement Slight improvement: so remaining (i.e. remaining elevation) No change from b Worse	ficant clearance (about small ulceration significant improvement and perceptible border extra intermediate between the improvement (about ulcers with only minute: Fields ending with '_n' of dending '_d' which contains	ent (about 75%); how ough have decreased elevation) een slight and marked out 25%); however, si nor decrease in size, e	ever, a small am in size, minimal i; representing a gnificant disease rythema or bord they have a correspondence	f dusky $\square_{(1)}$ fount of $\square_{(2)}$ bout $\square_{(3)}$ e $\square_{(4)}$ ponding $\square_{(5)}$			

Data entered:

5 " 1 " 1 " 1 " 1 " 1 " 1 " 1 " 1 " 1 "			
Participant ID:			
Participant initials:			

WEEK 2 CRF



None	No erythema	(o)
Slight	Mild pink colour	<u> </u>
Moderate	Moderate pink colour	<u></u>
Severe	Reddish colour	<u>(3)</u>
Very severe	Dark red or violaceous	<u></u>
Border elevation	belev_n	
None	Border is flat with ulcer and surroun and surroun ion	(o)
Slight	Slight elevation of border above ulceration and surrounding skin	<u></u>
Moderate	Noticeable elevation of border above ulceration and surrounding skin	<u></u> (2)
Severe	Significant elevation of border above ulceration and surrounding skin	<u></u> (3)
Very severe	Border rolled high above ulceration and surrounding skin	<u></u>
Exudate		
None	Wound is dry exud_n	(o)
Slight	Spotting of clear fluid	<u></u>
Moderate	Moderate amount of discharge, partially discoloured	<u> </u>
Severe	Heavy, discoloured discharge	<u></u>
Very severe	Copious, offensive or blood stained discharge	 (4)

not entered

SECTION 6 – TRIAL CHECKLIST			
For patients in either the RCT or observational study, have the	Yes	No	NA
following been done?			
H Arranged follow-up appoints	□ ₍₁₎	(o)	<u></u> (8)
Completed the <i>Trial Medication change log</i> if applicable	□ ₍₁₎	(o)	□ ₍₈₎
Recorded this visit in the hospital notes	□ ₍₁₎	□ ₍₀₎	
ients in the RCT only, have the following been done?			

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week 2 CRF FINAL v2.5 050310 **Data entered:**

Participant ID:			
•			
Participant initials:			

WEEK 2 CRF



articipant initials.		VVV	ww.stopgaptilai.co.uk
Routine samples as you would in normal care? Recommended samples are: full blood count, urea & electrolytes, CRP,		(o)	
rheumatoid factor, auto-antibodies, ANCA, serum immunoglobulins, ulcer swab for bacteriology			
Urine pregnancy test (women of child-bearing potential only) and pregnancy advice	(1)	□(o)	□ ₍₈₎
Completed the <i>Adverse Event log</i> if applicable	□ ₍₁₎	□(o)	□ ₍₈₎
	-	1	-

SECTION 7 – CRF SIGN-OFF		
I confirm that the information conf	tained in this CRF is accurate to the best of my knowledge:	
Signed	Date	

- Please send the TOP copy of all sheets in this CRF to the co-ordinating centre in the envelope provided in the patient file.
- BOTTOM copies should be filed in the patient file
- Please consider this patient for systemic therapy if the disease is not controlled on topical therapy



Date of completion D M M M Y Y Y Y Compdat

We are interested in your thoughts about the ulcer your doctor is assessing

1. Overall since your **first** appointment, how much has your ulcer improved?

0	Completely clear (skin colour may have changed)	□ ₍₀₎
1	Almost clear (about 90% improvement)	(1)
2	Marked improvement (about 75% improvement)	(2)
Ŋ	Moderate improvement (about 50% improvement)	(3)
4	Slight improvement (about 25% improvement)	(4)
5	No change	(5)
6	Worse	(6)

2. Please assess your ulcer by completing the table below:

uimp_n

Colour (please tick one option in this section)						
None	No redness	□ ₍₀₎				
Slight	Mild pink colour	1 (1)				

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week 2 patient

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Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK 2



www.stopgaptrial.co.uk Moderate Moderate pink colour ucol_n (2) Reddish colour Severe (3) Very severe Dark red or purple colour (4) Thickness of the edge of the ulcer (please tick *one* option in this section) None Border is flat with ulcer and surrounding skin, no thickening \square (0) Slight Slight thickening of border above ulceration and surrounding \square ₍₁₎ skin Noticeable thickening of border above ulceration and Moderate uthick_n (2) surrounding skin Severe Significant thickening of border above ulceration and (3) surrounding skin Border rolled high above ulceration and surrounding skin Very severe (4) **Pus or discharge** (please tick *one* option in this section) None Wound is dry (O) Spotting of clear fluid Slight \square ₍₁₎ <mark>upus_n</mark> Moderate Moderate amount of discharge, partially discoloured (2) Severe Heavy, discoloured discharge (3) Copious, offensive or blood stained discharge Very severe

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'_d' with the short text description

week 2 patient

(4)

Note: Fields ending 'n' contain the numeric entry; they have a corresponding field ending

Participant ID:					
Participant initials:		P/	TIE	NT C	UESTIONNAIRE WEEK 2



Thank you for taking the time to fill in this questionnaire. Once completed, please return it in the stamped addressed envelope provided to:

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

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week 2 patient

	Participant ID: Participant initials				WEEK		Stop gap www.stopgaptrial.co.uk
VISIT	S						
	Date of visit	D D		M Wisda	M Y	Y	Y
PHYEX	AM		<mark>pendi</mark>	ng en			
	SECTION 1 – PHY	SICAL EXAMI	NATIO	ON			
	Measurement of tar	get lesion	Max	longitudinal length (m	m)	leslon_t	t
			Max	perpendicular width (r	mm)	lesper_	t
	PG status		Targe	et lesion healed – no lo	onger using dressin	gs	□ ₍₁₎
	pgsta	at_n	Targe	et lesion still requiring	treatment		□ ₍₂₎
			Targe	et lesion healed but on	going treatment fo	or other lesions	□ ₍₃₎
			D	D M	M M	Y	Y
CDR	UG	pe	nding			_	
	SECTION 2 – MEI	DICATION				Yes	No
	Is Is the patient cur the following drugs?		y of	Methotrexate	meth_n	□(1)	□(o)
				Azathioprine	<mark>azat_n</mark>		□(o)
				Leflunomide	<mark>lefl_n</mark>	□(1)	□(o)
		pending CTION 1 - PHYSICAL EXAMINATION Target lesion healed - no longer using dressings Target lesion still requiring treatment Target lesion healed but ongoing treatment for other lesions Target lesion healed but ongoing treatment for other lesions Target lesion stopped requiring pending CTION 2 - MEDICATION Is the patient currently taking any of following drugs? Atathioprine azat Care Care Care Care Care Care Anti-TNF atnf_n Care Care Care Anti-TNF atnf_n Care Care Mycophenolate Myco_n Care Tetracyclines Care Care					
			pending CAL EXAMINATION Lesion Max longitudinal length (mm) lesion_t Max perpendicular width (mm) Target lesion healed – no longer using dressings Target lesion still requiring treatment Target lesion healed but ongoing treatment for other lesions Target lesion healed but ongoing treatment for other lesions Pending Pending Pending Pending Pending Pending Pending Perding P				
		pending pending pending I - PHYSICAL EXAMINATION Int of target lesion Max longitudinal length (mm) Max perpendicular width (mm) Target lesion healed – no longer using dressings Target lesion healed but ongoing treatment Target lesion still requiring treatment Target lesion healed but ongoing treatment for other lesions pending Pend					
				Mycophenolate	<mark>myco_n</mark>	□(1)	□(o)
	treatment that could	influence		If yes, please give det	tails of drug name	s) (dose not requ	ired):
	Yes□(1) No□(2)	other_n		othdet1	othdet2		

Participant ID:			
•			
Participant initials:			

WEEK 6 CRF



IGAEFF	pending	

Since th	e BASELINE visit, has the target lesion improved?	
Grade		Tick belov
0	Completely clear: except for possible residual hyperpigmentation	(o)
1	Almost clear: very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration	□ ₍₁₎
2	Marked improvement: significant improvement (about 75%); however, a small amount of disease remaining (i.e. remaining ulcers, although have decreased in size, minimal lesimp_n – contains numeric value; also field with '_d' ending containing text description	<u></u> (2)
3	Moderate improvement: intermediate between slight and marked; representing about 50% improvement	□ ₍₃₎
4	Slight improvement: some improvement (about 25%); however, significant disease remaining (i.e remaining ulcers with only minor decrease in size, erythema or border elevation)	(4)
5	No change from baseline	□ ₍₅₎
	Worse	□ ₍₆₎

/14		benamb							
JLCI	ION 4 – IN	FLAMMATION AS	ESSMENT OF THE	TARGET LESIO	N				
Pleas	Please tick one box only for each section								
Eryth	Erythema								
None	None No erythema $\square_{(0)}$								
Slight		Mild pink col	ur		7	<u></u>			
Mode	rate	Moderate pir	k colour	<mark>eryth_n</mark>		<u></u> (2)			
Sever	e	Reddish colo	r		-	(3)			
Very	Very severe Dark red or violaceous					 (4)			
Borde	r elevation								
None		Border is flat	with ulcer and surroun	ding skin, no elevo	ation	(o)			
Slight		Slight elevati	n of border above ulce	eration and surrou	ınding skin	(₁₎			
Mode	rate	Noticeable ei skin	evation of border a	belev_n	ırrounding	(₂)			

week 6 CRF FINAL v2 041209 data entered:

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Participant ID:				
•				
Particinant initials:	l			

WEEK 6 CRF

Stop	
www.stopgaptrial.co.u	k

Participant in	nitials:	www.stopgaptrial.co.uk	
Severe	Significant elevation of border above ulceration and surrounding skin	<u></u>	
Very severe	Border rolled high above ulceration and surrounding skin	<u></u> (4)	
Exudate			
None	Wound is dry	(o)	
Slight	Spotting of clear fluid		
Moderate	Moderate amount of discharge exud_n	<u>(2)</u>	
Severe	Heavy, discoloured discharge	<u>(3)</u>	
Very severe	Copious, offensive or blood stained discharge	<u></u> (4)	
Note: fields ending '_n' contain the numeric value; they have a corresponding field ending '_d' containing the short text description			
,			

not entered

SECTION 5 – TRIAL CHECKLIST			
For patients in either the RCT or observational study, have the following been done?	Yes	No	NA
Completed the <i>Trial Medication change log</i> if applicable		□ ₍₀₎	□ ₍₈₎
Recorded this visit in the hospital notes		□ ₍₀₎	
ients in the RCT only, have the following been done?			
Routine samples as you would in normal care? Recommended samples are: full blood count, urea & electrolytes, CRP, rheumatoid factor, auto-antibodies, ANCA, serum immunoglobulins, ulcer swab for bacteriology	(₁)	(o)	
Urine pregnancy test (women of child-bearing potential only) and pregnancy advice		(o)	□ ₍₈₎
Digital images of the target lesion Please refer to the digital image guidance in Section 5 of this	□ ₍₁₎	□(o)	
Remember to take the image of the same lesion you took an image of at the baseline appointment			
Completed the <i>Adverse Event log</i> if applicable		(o)	□ ₍₈₎

SECTION 6 – CRE SIGN-OFF		

Participant ID: Participant initials:		WEEK 6 CRF	www.stopgaptrial.co.uk
I confirm that the i	nformation contained in this CRF is accur	rate to the best of my knowledge:	
Signed	 Date		

- Please send the TOP copy of all sheets in this CRF to the co-ordinating centre in the envelope provided in the patient file.
- BOTTOM copies should be filed in the patient file
- Please consider this patient for systemic therapy if the disease is not controlled on topical therapy

Stop

	Particip Particip	ant ID: ant initials: PATIENT QUESTIONNAIRE WEEK 6 www.stopgaptrial.co.uk	Stop
VISITS	Date	e of D D M M M Y Y	TY TY
	comple		
PQ	are in	nterested in your thoughts about the ulcer your doctor is	assessing
1.	Ove	erall since your first appointment, how much has your ulc	er improved?
	0	Completely clear (skin colour may have changed)	(o)
	1	Almost clear (about 90% improvement)	□ ₍₁₎
uimp_n	2	Marked improvement (about 75% improvement)	□(2)
<u>ump_n</u>	3	Moderate improvement (about 50% improvement)	□ ₍₃₎
	4	Slight improvement (about 25% improvement)	□(4)
	5	No change	□ ₍₅₎
	6	Worse	□ ₍₆₎

2. Please assess your ulcer by completing the table below:

Colour (please tick one option in this section)			
None	No redness	□ ₍₀₎	
Slight	Mild pink colour	□ ₍₁₎	

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week 6 patient

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Participant ID:					
Participant initials:		PA	TIE	NT Q	UESTIONNAIRE WEEK 6
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Moderate	Moderate pink colour
Severe	Reddish colour
Very severe	Dark red or purple colour
Thickness of t	he edge of the ulcer (please tick one option in this section)
None	Border is flat with ulcer and surrounding skin, no thickening
Slight	Slight thickening of border above ulceration and surrounding skin
Moderate	Noticeable thickening of border above ulceration and surrounding skin
Severe	Significant thickening of border above ulceration and surrounding skin
Very severe	Border rolled high above ulceration and surrounding skin
Pus or dischar	ge (please tick one option in this section)
None	Wound is dry
Slight	Spotting of clear fluid
Moderate	Moderate amount of discharge, partially discoloured
Severe	Heavy, discoloured discharge
Severe	

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containing the short text description

Note: fields ending '_n' contain the numeric value; they have a corresponding field ending '_d'

week 6 patient

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK 6



By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

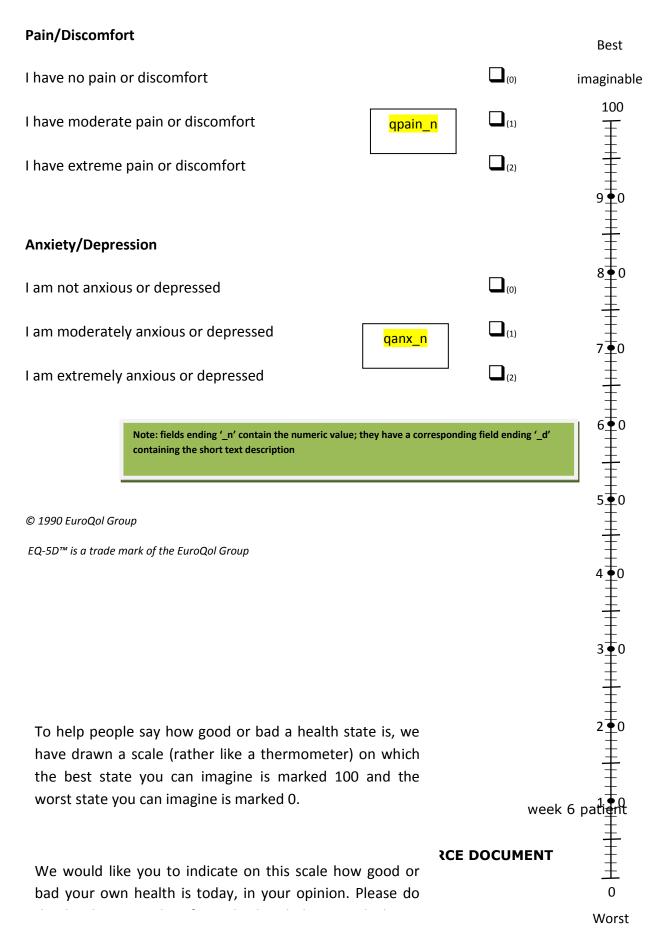
Mobility	
I have no problems in walking about	 (0)
I have some problems in walking about qmob_n	(1)
I am confined to bed	(2)
Self-Care	
I have no problems with self-care	(O)
I have some problems washing or dressing myself	(1)
I am unable to wash or dress myself	(2)
Usual Activities (e.g. work, study, housework, family or	
leisure activities) qact_n	
I have no problems with performing my usual activities	(O)
I have some problems with performing my usual activities	 (1)
I am unable to perform my usual activities	 (2)

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week 6 patient

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Participant ID:					
Participant initials:		P/	TIE	NT C	UESTIONNAIRE WEEK 6



Your own health state



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week 6 patient

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Participant initials:		P/	ATIE	NT C	UESTIONNAIRE WEEK 6



Note: fields ending '_t' contain the actual text entry; they have a corresponding field ending '_n' containing the numeric equivalent if appropriate

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week 6 patient

Participant ID:								
Participant initials:		PATIENT QUESTIONNAIRE WEEK 6						
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week 6 patient

Participant ID:					
Participant initials:		P/	TIE	NT C	UESTIONNAIRE WEEK 6



DLQI

matology Life Quality Index

Score	
dscore	

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The aim of this questionnaire is to measure how much your skin problem has affected your life **over the last** week. Please tick one box for each question.

Over the last week, how itchy , sore , painful or stinging has	Very much	□ ₍₃₎	
your skin been? ditch_n	A lot	□(2)	
	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	
Over the last week, how embarrassed or self conscious have	Very much	□ ₍₃₎	
you been because of your skin? demb_n	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	
Over the last week, how much has your skin interfered with	Very much	□ ₍₃₎	
you going shopping or looking after your home or garden? dshop_n	A lot	□ ₍₂₎	
<u> </u>	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much has your skin influenced the	Very much	□ ₍₃₎	
clothes you wear? dclothes n	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much has your skin affected any	Very much	□ ₍₃₎	
social or leisure activities?			
EudraCT Number 2008-008291-14Page 79 d dsocial_n		week 6	patient

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Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK 6



	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much has your skin made it	Very much	□ ₍₃₎	
difficult for you to do any sport ?	A lot	□ ₍₂₎	
dsport_n	A little	 (1)	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, has your skin prevented you from	yes	□ ₍₁₎	
working or studying? dwork_n	no	□ ₍₀₎	Not relevant □(8)
If "No", over the last week how much has your skin been a	A lot	□ ₍₂₎	
problem at work or studying ? dwmuch_n	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	
Over the last week, how much has your skin created	Very much	□ ₍₃₎	
problems with your partner or any of your close friends or relatives?	A lot	□ ₍₂₎	
dpart_n	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much has your skin caused any	Very much	□ ₍₃₎	
sexual difficulties? dsex_n	A lot	□ ₍₂₎	
	A little	 (1)	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much of a problem has the	Very much	□ ₍₃₎	
treatment for your skin been, for example by making your home messy, or by taking up time? dtreat_n	A lot	□ ₍₂₎	
EudraCT Number 2008-008291-14Page 80 o		week 6	patient

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Participant ID:					
Participant initials:		P.A	TIE	NT C	UESTIONNAIRE WEEK 6



		A little	 (1)	
		Not at all	□ ₍₀₎	Not relevant □(8)
©AY Finlay, GK Khan, April 1992, This must no	Note: fields ending '_n' contain the nume containing the short text description	ric value; they have	a correspon	ding field ending '_d'

Thank you for taking the time to fill in this questionnaire. Once completed, please return it in the stamped addressed envelope provided to:

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

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week 6 patient







STOP GAP RESEARCH STUDY

PATIENT DIARY 2 (+6 WEEKS)

RCT patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

Participant ID:					
Participant initials:		P.A	TIE	NT C	UESTIONNAIRE WEEK 6
					www.stopgaptrial.co.uk



- Whether your pyoderma gangrenosum has affected your daily activities
- Whether you are still using dressings for your ulcer
- Any illnesses you have experienced
- Any visits you have made to your GP or hospital

This diary should be completed **every day** until your ulcer has healed or after 6 months since you started your tablets (whichever comes first).

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8230489 or 0115 8230486**



Your local STOP GAP study doctor is:

Name	
Hospital name	
Telephone number	

Participant ID:						
Participant initials:		PA	TIE	NT Q	QUESTIONNAIRE WEEK 6	



The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Julie Barnes
Address	Nottingham Clinical Trials Unit Office B39, Medical School Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8230489 / 0115 8230486
Email address	stopgap@nottingham.ac.uk

Participant ID:					
Participant initials:		PA	TIEI	NT C	QUESTIONNAIRE WEEK 6



If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.



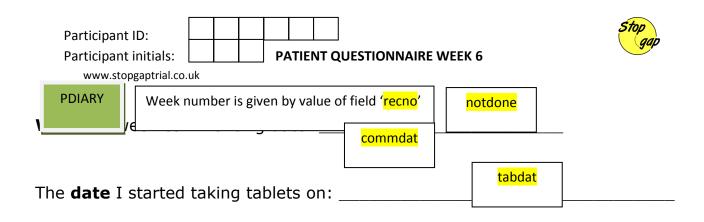
It is important, however, that you **do not** stop taking the tablets suddenly as this can be very dangerous. Please talk to your doctor first who will be able to advise you what to do.

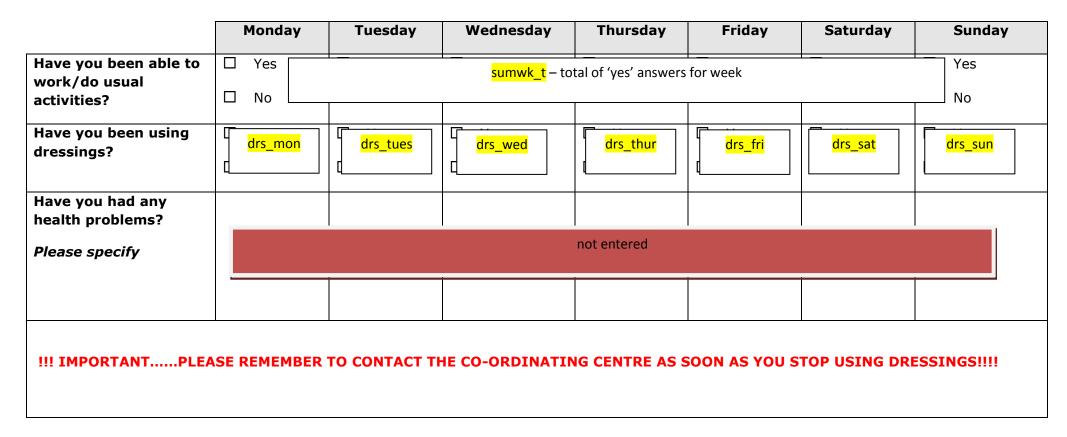


It is also important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

not entered

The ulcer being studied is:









Please tick if you have a	ccessed any o	f the following b	ecause of your pyo	derma gangre	nosum or beca	use of possible	side-effects of			
the medication										
GP Surgery		gps t – total of ticked answers for week								
GP Home		T	gph t – total of ticked	l answers for week	Ţ					
Practice Nurse			pn t – total of ticked	answers for week						
District Nurse		dn t – total of ticked answers for week								
Out Patient	_ П		П	П	П					
Appointment			opa t – total of ticked	l answers for week						
In Patient			ip t – total of ticked	answers for week						
Other, please specify:	_	oth t – total of ticked answers for week								
		othdet1 othd	et2 othdet3							

Participant ID:						
Participant initials:			P.A	TIE	NT C	UESTIONNAIRE WEEK
www.stopgaptrial.co.	uk					



WEEK 2: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	□ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes
, 40 4040 4041	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you been using dressings?	□ Yes	□ Yes	□ Yes	☐ Yes	□ Yes	☐ Yes	☐ Yes
aressings.	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you had any health problems?							
Please specify							

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK



the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

Participant ID:						
Participant initials:			P/	ATIE	NT C	UESTIONNAIRE WEEK
www.stopgaptrial.co.	uk					



WEEK 3: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	□ Yes	☐ Yes	☐ Yes
	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you been using dressings?	□ Yes	☐ Yes	☐ Yes	□ Yes	□ Yes	□ Yes	□ Yes
uressings.	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you had any health problems?							
Please specify							

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK



the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

Participant ID:						
Participant initials:			P/	TIE	NT C	UESTIONNAIRE WEEK
www.stopgaptrial.co.	uk					



WEEK 4: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	□ Yes	☐ Yes
	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you been using dressings?	□ Yes	☐ Yes	☐ Yes	☐ Yes	□ Yes	□ Yes	□ Yes
uressings.	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you had any health problems?							
Please specify							

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK



the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

						1
Participant ID:						
Participant initials:			P/	ATIEI	NT C	UESTIONNAIRE WEEK (
www.stopgaptrial.co.	uk					



WEEK 5: week commencing date: _____

	ı	Monday	Tuesday	V	Vednesday	Т	hursday	Friday	S	Saturday	Sunday
Have you been able to work/do usual activities?		Yes	Yes		Yes		Yes	Yes		Yes	Yes
Nony do dodar delivities.		No	No		No		No	No		No	No
Have you been using dressings?		Yes	Yes		Yes		Yes	Yes		Yes	Yes
3		No	No		No		No	No		No	No
Have you had any health problems?											
Please specify											

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK



the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

De altata a di ID							
Participant ID:							
Participant initials:				P/	TIE	NT C	UESTIONNAIRE WEEK
www.stopgaptrial.co.	uk						



WEEK 6: week commencing date: _____

	ı	Monday	7	Tuesday	V	Vednesday	Т	hursday	Friday	S	aturday	Sunday
Have you been able to work/do usual activities?		Yes		Yes		Yes		Yes	Yes		Yes	Yes
		No		No		No		No	No		No	No
Have you been using dressings?		Yes		Yes		Yes		Yes	Yes		Yes	Yes
		No		No		No		No	No		No	No
Have you had any health problems?												
Please specify												

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE WEEK



the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

Participant ID:						
Participant initials:			P/	ATIE	NT C	UESTIONNAIRE WEEK
www.stopgaptrial.co.	uk					



WEEK 7: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	□ Yes	☐ Yes	☐ Yes
	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you been using dressings?	□ Yes	☐ Yes	☐ Yes	□ Yes	□ Yes	□ Yes	□ Yes
uressings.	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you had any health problems?							
Please specify							

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	QUESTIONNAIRE WEEK



the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

Participant ID:							
Participant initials:				P/	TIE	NT C	QUESTIONNAIRE WEEK
www.stopgaptrial.co.	uk						



WEEK 8: week commencing date: _____

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Have you been able to work/do usual activities?	□ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes
, 40 4040 4041	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you been using dressings?	□ Yes	□ Yes	□ Yes	☐ Yes	□ Yes	☐ Yes	☐ Yes
aressings.	□ No	□ No	□ No	□ No	□ No	□ No	□ No
Have you had any health problems?							
Please specify							

!!! IMPORTANT......PLEASE REMEMBER TO CONTACT THE CO-ORDINATING CENTRE AS SOON AS YOU STOP USING DRESSINGS!!!!

Participant ID:					
Participant initials:		PA	TIE	NT C	QUESTIONNAIRE WEEK

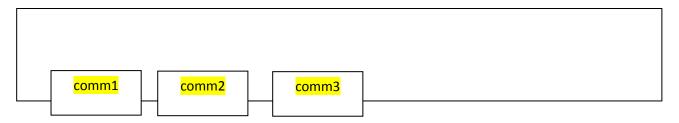


the medication				
GP Surgery				
GP Home				
Practice Nurse				
District Nurse				
Out Patient Appointment				
In Patient				
Other, please specify:				

Participant ID:					
Participant initials:		PA	ATIEI	NT C	UESTIONNAIRE WEEK 6



Pa	rticipant initials:		PATIENT QUESTIONNA	IRE WEEK 6 www.stopgaptri	al.co.uk	•
	you started	your	not entered		have you taker	າ your tablets
	Every day					
	Most days			_		
	Some days		<mark>tabtake</mark>			
	Never					
If you	ı would like to	o add any o	comments, please	do so here	e:	

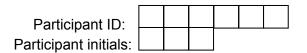


Please now record any prescriptions you have been given for your pyoderma gangrenosum (e.g tablets, creams, dressings, bandages etc).

Participant ID:					
Participant initials:		P/	TIE	NT C	UESTIONNAIRE WEEK 6



Prescription type / name of medicine	Dose / number of items (if applicable)
pres1	pres1dos
pres2	pres2dos
pres3	pres3dos
pres4	pres4dos
pres5	pres5dos
pres6	pres6dos



FINAL VISIT CRF



	TS	of visit	D	D		M	visdat		Υ		Υ	Υ		Υ
YEX	_								pending					
	3LCH(ON 1 – I	PHYSICAL	EXAMI	NATI	ON							7	
	Measur	ement o	f target lesio	on	Max	longitu	dinal length (m	m)		_	leslor			
					Max	perpen	dicular width (ı	nm)		L	<mark>lespe</mark>	'_ ^L		
			s on entire l	body							ulc_	t		
	PG stat	us			_	et lesior sings	n healed – no lo	onger i	using					
			pgstat_	<mark>_n</mark>	Targ	et lesior	n still requiring	treatn	nent	☐(2	2)			
							n healed but or or other lesions			<u></u> (3	3)			
		esion sto	e date that t pped requir		D	D	M	M pgst	cop	Υ	Υ		Υ	Υ
CDR	UG						pending	\neg						
	SECTION	ON 2 – I	MEDICATI	ON			pending	┵			Yes		No	
		e patient owing dr	t currently to	aking an	y of	Metho	otrexate		meth_n		□ ₍₁₎		□(o)	
						Azath	ioprine		<mark>azat_n</mark>		□ ₍₁₎		□(o)	
						Leflun	nomide		<mark>lefl_n</mark>		<u></u> (1)		□(o)	
						Anti-T	NF		atnf_n		□ ₍₁₎		□(o)	
						aptopurine P, Puri-Nethol [®])		<mark>pure_n</mark>		□ ₍₁₎		□(o)		
							cyclines		<mark>tetr_n</mark>		□ ₍₁₎		□(o)	
				Mycophenolate myco_n					<u></u> (1)		□(o)			
		-	taken any ot			If yes,	please give de	tails o	f drug name	e(s) (e	dose not r	equire	d):	
			could influer	nce										
		ma gangr No□(2)	renosum?	other_n			othdet1		othdet2					

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Final visit CRF FINAL v2: 041209 Data entered:

Participant ID:			
i artioipant ib.			
Participant initials:			

FINAL VISIT CRF



IGAEFF	

pending

Since the B A	ASELINE visit, has the target lesion improved?	
Grade		Tick below
0	Completely clear: except for possible residual hyperpigmentation	(o)
1	Almost clear: very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration	□ ₍₁₎
2	Marked improvement: significant improvement (about 75%); however, a small amount of	(₂₎
esimp_n	disease remaining (i.e remaining ulcers, although have decreased in size, minimal erythema and/or barely perceptible border elevation)	
3	Moderate improvement: intermediate between slight and marked; representing about 50% improvement	(3)
4	Slight improvement: some improvement (about 25%); however, significant disease remaining (i.e remaining ulcers with only minor decrease in size, erythema or border elevation)	(4)
5	No change from baseline	(₅₎
6	Worse	(₆)

SLETION 4 – INFLAMMATION ASSESSMENT OF THE TARGET LESION								
Please tick one box only for each section								
Erythema								
None	No erythema		(₀)					
Slight	Mild pink colour		(₁₎					
Moderate	Moderate pink colour	<mark>eryth_n</mark>						
Severe	Reddish colour	□ ₍₃₎						
Very severe	Dark red or violaceous	<u></u>						
Border elevation								
None	Border is flat with ulcer and surrounding	Border is flat with ulcer and surrounding skin, no elevation $\Box_{(0)}$						
Slight	Slight elevation of border above ulceration	<u></u>						
Moderate	Noticeable elevation of border above ulc skin	belev_n ding	□ ₍₂₎					
Severe	Significant elevation of border above ulc	eration and surrounding	□ ₍₃₎					

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Final visit CRF FINAL v2: 041209 Data entered:

PLEASE NOTE THIS IS A SOURCE DOCUMENT

Participant ID:			
r artiolparit iB:			
rticipant initials:			

FINAL VISIT CRF

Stop
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articipant initials: [W	ww.stopgaptrial.co.u					
	skin								
ery severe	Border rolled high above ulceration and su		(4)						
kudate									
one	Wound is dry			(o)					
ight	Spotting of clear fluid		<u></u>						
oderate	Moderate amount of discharge, partiall exudh_n								
evere	Heavy, discoloured discharge	(3)							
ery severe	Copious, offensive or blood stained dischar		(3) (4)						
	Note: fields ending '_n' contain the numeric value, containing the short text description	and have correspond	ling fields ending '_c	ľ					
	Not entered								
SECTION 5 – TRIA	AL CHECKLIST								
For patients in either following been done	r the RCT or observational study, have the	Yes	No	NA					
Completed the <i>Tri</i>	ial Medication change log if applicable		(o)	□ ₍₈₎					
Recorded this visi	it in the hospital notes	<u></u> (1)	(o)						
•	have the following been done?								
Recommended samples	you would in normal care? s are: full blood count, urea & electrolytes, CRP, o-antibodies, ANCA, serum immunoglobulins, logy	(1)	(o)						
•	t (women of child-bearing potential only)		(o)	□ ₍₈₎					
•	gital image guidance in Section 5 of this	□ ₍₁₎	□ ₍₀₎						
	olete the digital image log ne image of the same lesion you took an line appointment								
Completed the Adve	rse Event log if applicable	(₁)	□(o)	□ ₍₈₎					
SECTION 6 – CRF									
I confirm that the in	formation contained in this CRF is accurate to	the best of my k	nowledge:						

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Final visit CRF FINAL v2: 041209

Data entered:

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Participant ID:					FINAL VISIT CRF	Stop	
Participant initials:							www.stopgaptrial.co.uk

- Please send the TOP copy of all sheets in this CRF to the co-ordinating centre in the envelope provided in the patient file.
- BOTTOM copies should be stored in the patient file
- The co-ordinating centre will be in touch with the participant now they have completed the trial

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Final visit CRF FINAL v2: 041209 **Data entered:**

	Particip Particip	oant ID:	P	ATIENT	QUESTIONNAIR		_ gaptrial.co	.uk	Stop	gap	
PQ	ate		D	М	<mark>compdat</mark>]	Υ	Υ	Y	stdat	
				<u> </u>							
we 1.					about the ul atment, how					_	
	0	Completel	□ ₍₀₎								
	1	Almost cle	□ ₍₁₎								
<mark>uimp_n</mark>	2	Marked im	□ ₍₂₎								
	3	Moderate	improvemen	t (abo	ut 50% impr	oveme	ent)		□ ₍₃₎		
	4	Slight imp	rovement (a	bout 2	25% improve	ment)			☐ ₍₄₎		
	5	No change	9						□ ₍₅₎		
	6 Worse										
. Plea	Please assess your ulcer by completing the table below:										
	Colour (please tick one option in this section) None No redness										

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(1)

final patient

Mild pink colour

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Slight

<mark>ucol_n</mark>

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE FINAL



Г			1
	Moderate	Moderate pink colour	□ ₍₂₎
	Severe	Reddish colour	□ ₍₃₎
	Very severe	Dark red or purple colour	☐(4)
	Thickness of the	edge of the ulcer (please tick one option in this section)	
	None	Border is flat with ulcer and surrounding skin, no thickening	(o)
	Slight	Slight thickening of border above ulceration and surrounding skin	□ ₍₁₎
	Moderate	Noticeable thickening of border above ulceration and surrounding skin	□ ₍₂₎
	Severe	Significant thickening of border above ulceration and surrounding skin	☐(3)
-	Very severe	Border rolled high above ulceration and surrounding skin	□ ₍₄₎
Ī	Pus or discharge	(please tick one option in this section)	
	None	Wound is dry	□ ₍₀₎
-	Slight	Spotting of clear fluid	□ ₍₁₎
	Moderate	Moderate amount of discharge, partially discoloured	□ ₍₂₎
	Severe	Heavy, discoloured discharge	☐(3)
	Very severe	Copious, offensive or blood stained discharge	☐(4)
	nding with '_n' contain the non- hort text description	umeric value; they have corresponding fields ending '_d' which	

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<mark>uthick_n</mark>

<mark>upus_n</mark>

EQ5D

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE FINAL



By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility							
I have no problems in walking about		(O)					
I have some problems in walking about	<mark>qmob_n</mark>	(1)					
I am confined to bed		(2)					
Self-Care							
I have no problems with self-care		 (0)					
I have some problems washing or dressing myself							
I am unable to wash or dress myself	<mark>qcare_n</mark>	(2)					
Usual Activities (e.g. work, study, housework, fam	ily or						
leisure activities)							
I have no problems with performing my usual activ	vities	(0)					
I have some problems with performing my usual a	ctivities	(1)					
I am unable to perform my usual activities	<mark>qact_n</mark>	(2)					

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final patient

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Pain/Discomfort		Best
I have no pain or discomfort	(0)	imaginable
I have moderate pain or discomfort qpain_n	(1)	100 王
I have extreme pain or discomfort	(₂₎	± ±
Anxiety/Depression		9 ∲ 0
I am not anxious or depressed	(o)	8 ∳ 0
I am moderately anxious or depressed	— (1)	± = = = = = = = = = = = = = = = = = = =
I am extremely anxious or depressed		/ Q 0
Note: fields ending with '_n' contain the numeric value; they have corresponding field contain the short text description	s ending '_d' which	6 ∮ 0
© 1990 EuroQol Group		5 • 0
EQ-5D™ is a trade mark of the EuroQol Group		+
The state of the Larone Group		4 0
		‡ <u>‡</u>
		3 • 0
		<u>‡</u>
To help people say how good or bad a health state is, we		2 • 0
have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the		<u>‡</u>
worst state you can imagine is marked 0.	1	final patient
We would like you to indicate on this scale how good or	RCE DOCUMENT	· ‡
bad your own health is today, in your opinion. Please do		0 Worst

imaginable

Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE FINAL



Your own health state

hstate_t

final patient

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Participant ID:					
Participant initials:		P/	TIEI	NT C	UESTIONNAIRE FINAL



Note: fields ending with '_t' contain the actual text input; they have corresponding fields ending '_n' which contain the numeric value if appropriate

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Participant ID:					
Participant initials:		P/	ATIEI	NT Q	UESTIONNAIRE FINAL
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Participant ID:					
Participant initials:		P/	TIE	NT C	UESTIONNAIRE FINAL



DLQI

natology Life Quality Index

Score	
<mark>dscore</mark>	

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The aim of this questionnaire is to measure how much your skin problem has affected your life **over the last** week. Please tick one box for each question.

Over the last week, how itchy , sore , painful or s	tinging has	Very much	□ ₍₃₎	
your skin been?	ditch_n	A lot	□ ₍₂₎	
	utteri_ii	A little	□ ₍₁₎	
		Not at all	□ ₍₀₎	
Over the last week, how embarrassed or self co	nscious have	Very much	□ ₍₃₎	
you been because of your skin?	demb_n	A lot	□ ₍₂₎	
	<u></u>	A little	□ ₍₁₎	
		Not at all	□ ₍₀₎	
Over the last week, how much has your skin inte		Very much	□ ₍₃₎	
you going shopping or looking after your home (or garden? dshop_n	A lot	□ ₍₂₎	
		A little	□ ₍₁₎	
		Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much has your skin infl	uenced the	Very much	□(3)	
clothes you wear?	dclothes_n	A lot	□ ₍₂₎	
		A little	□ ₍₁₎	
		Not at all	□(0)	Not relevant □(8)
Over the last week, how much has your skin affe social or leisure activities?	ected any	Very much	□ ₍₃₎	
EudraCT Number 2008-008291-14Page 11 questionnaire_v1_310309	dsocial_n		final	patient

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Participant ID:					
Participant initials:		PA	TIE	NT C	UESTIONNAIRE FINAL



	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, how much has your skin made it	Very much	□ ₍₃₎	
difficult for you to do any sport ?	A lot	□ ₍₂₎	
dsocial_n	A little	 (1)	
	Not at all	□ ₍₀₎	Not relevant □(8)
Over the last week, has your skin prevented you from	yes	□ ₍₁₎	
working or studying? dwork_n	no	□ ₍₀₎	Not relevant □(8)
If "No", over the last week how much has your skin been a	A lot	□ ₍₂₎	
problem at work or studying ? dwmuch_n	A little	□ ₍₁₎	
	Not at all	□ ₍₀₎	
Over the last week, how much has your skin created	Very much	□ ₍₃₎	
problems with your partner or any of your close friends or relatives? dpart_n	A lot	□(2)	
	A little	□ ₍₁₎	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much has your skin caused any	Very much	□ ₍₃₎	
sexual difficulties? dsex_n	A lot	□ ₍₂₎	
	A little	□ ₍₁₎	
	Not at all	□(o)	Not relevant □(8)
Over the last week, how much of a problem has the	Very much	□ ₍₃₎	
treatment for your skin been, for example by making vour home messy, or by taking up time? dtreat_n	A lot	□ ₍₂₎	

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Participant ID:					
Participant initials:		P/	TIE	NT C	UESTIONNAIRE FINAL



		A little	 (1)	
		Not at all	□ ₍₀₎	Not relevant □(8)
©AY Finlay, GK Khan, April	Note: fields ending with '_n' contain the numeric value; they contain the short text description	nave corresponding	fields endinį	g '_d' which

Thank you for taking the time to fill in this questionnaire. Once completed, please return it in the stamped addressed envelope provided to:

STOP GAP Trial Manager
Nottingham Clinical Trials Unit
Office B39, Medical School
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

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Participant ID: E Participant initials:	•							E	N
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END OF TRIAL CRF



We are interested to know whether the patient has had a recurrence of their pyoderma gangrenosum since they completed the trial

Please use the hospital notes to complete this form. We would like to know of any recurrences since <insert date of final visit>.

EOTCRF

Question		
number		
1	Since the date given above, has the patient had a	Yes, go to Q2 No, go to Q3
	further episode of PG? furpg	res, go to Q2
2	If yes, what was the date of the first recurrence? frecdat	D D M M M Y Y Y
3	Following the patient's final study visit, how and you	
	treat them?	The trial drug was tapered \square
4		
	treat	Maintenance dose given
		Other (please specify)
		trtoth
4	Any further comments	
		comm1
		somm3
		comm2
		comm3

CRF SIGN-OFF								
I confirm that the information contained in this CRF is accurate to the best of my knowledge:								
Signed	 Date							

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end of trial CRF draft v0.1: 02.04.09 **Data entered:**

PLEASE NOTE THIS IS A SOURCE DOCUMENT

		 -	1	1		STOP
Participant ID:					END OF TRIAL CRF	gap
Participant initials:					www.s	stopgaptrial.co.u