

# STOP GAP Newsletter



Issue 6, August 2011

#### It's a girl for Eleanor!

As you know, Eleanor had a baby girl on 1st August and has asked me to pass this message on: "Thanks to all the investigators, up and down the country, who have sent in messages of congratulations following the birth of my daughter, Lucy Abigail. It really is lovely that so many of you took the time to do so and I am really touched. We are both doing well and my son, James, who is 4, also loves the new addition to the family and keeps showering her with kisses! I can't resist showing her off, so thought you might like to see a picture of her too! Keep up the good work with STOP GAP, Kath is keeping me updated with what is happening! Best wishes, Eleanor".



#### **Summary:**

TARGET

140

RECRUITED

82

TO RECRUIT

58

• TIME LEFT (months)

8

#### The top 5 centres

1 = Hull

2 = Aberdeen

3 = Exeter

4 = Selly Oak

5 = Leicester

#### What do you think?.....

We are always looking for ways to improve the recruitment into the STOP GAP study. Everyone is busy and has many things to think about so one thing we often struggle with is how to keep the study prominent in the minds of clinicians and all health professionals in your hospital. Thus we want to ask you......

What do you think will help to remember STOP GAP and keep it in your mind and indeed in those of your colleagues?

**Please take a moment** to consider this and email/call/send feedback to us so we can help you.

We will implement suggestions where possible!

It could be different ways of advertising the study locally or something to sit on your desk (e.g. note pad) ....the list is endless, but do let us know what you think.



# Welcome to the gang

I am sure you will join us in welcoming the investigators at the centres which have joined the STOP GAP trial in the last 3 months.

These are:

Reading (Dr Seukeran and team),

Taunton & Yeovil (Dr Wachsmuth and team)

If you have any queries about STOP GAP, please don't hesitate to contact us:

**Kath Foster** 

Trial Manager (mat leave) 0115 8844926

**Julie Barnes** 

Trial Administrator 0115 8844941

#### **Important reminders**

- For RCT patients, please **DO NOT** prescribe topical therapy (e.g. Dermovate or Protopic).
- DO NOT undertake any trial procedure until you have taken consent—this includes enrolling patients on the randomisation system
- Tips to help you with completion of CRFs:
  - Dates of birth, initials and ID numbers MUST be consistent
  - Complete all fields—do not leave anything blank (the total number of ulcers & whether the patient is taking any other meds are often left blank)
  - Ensure the lesion size recorded at baseline matches what you record on the randomisation system (note the different units used)

Please remember to file completed Data Query Forms with the completed CRF to ensure we have a full audit trail.



# **Images of lesions**

(RCT patients only)

The images taken for STOP GAP form the basis of our primary outcome and are therefore

absolutely **essential** to this study.

I cannot stress enough how important it is to obtain good images, using a target plate, at each of the specified visits.

That is **Baseline**, **Week 6** and **Final** visit. Sending them to us in a timely fashion is equally important so, if necessary, you have time to get the participant back if there are problems.

### **Screening logs**

Screening logs are **essential** to enable us to check trial progress. They allow us to identify specific issues locally to you which we can potentially help with and also issues which are important nationally which, if seen to be a barrier to effective recruitment for many centres, may require a protocol change to resolve.

However if we do not receive the screening logs we will never know if there are issues out there.

Please send monthly via fax to: 0115 9194430.

## **Interesting references**

You may be interested in the following papers which have recently been published.

Pyoderma gangrenosum after thoracic surgery. Esteve-Martinez A, et al. Ann Thorac Surg. 2011 Aug; 92(2):741

<u>Mutations in the PSTPIP1 gene and aberrant splicing variants in patients with pyoderma gangrenosum.</u>

Nesterovitch AB, *et al.* Clin Exp Dermatol. 2011 Jul 25.

<u>Pyoderma Gangrenosum: A Report of 15 Cases and Review of the Literature.</u> SuÃ<sub>i</sub>rez-Pérez JA, *et al.* Actas Dermosifiliogr. 2011 Jul 20. English, Spanish

<u>Pyoderma gangrenosum: variation in clinical presentation at different ages.</u> Girisha BS, *et al.* Indian J Dermatol. 2011 May; 56(3):355-7.

Beneficial effects of neutrophil-targeted therapy for pyoderma gangrenosum associated with ulcerative colitis. Ikeda K. et al. Eur J Dermatol. 2011 Jul 12.

<u>Pyoderma gangrenosum, acne, and suppurative hidradenitis (PASH)-a new autoinflammatory syndrome distinct</u> from PAPA syndrome. Braun-Falco M, *et al.* J Am Acad Dermatol. 2011 Jul 9.

Interleukin 23 Expression in Pyoderma Gangrenosum and Targeted Therapy With Ustekinumab. Guenova E, et al. Arch Dermatol. 2011 Jun 16.

## **Congratulations!**

To the following individuals who have received 'quarterly awards' - they have all made a significant contribution to the trial from April 2011 — June 2011.



Principal Investigator— Augustin Martin-Clavijo, Selly Oak Hospital

Nurse— Naomi Hare, St Thomas' Hospital