



STOP GAP Newsletter

Issue 2, January 2010



Thank you to you all for your continuing enthusiasm and effort in this trial succeed. This will be the largest ever trial in pyoderma gangrenosum, and you are therefore making a major contribution to the world literature on this rare condition.

Recruitment update

To date, we have recruited 15 patients into the RCT arm of the trial, and a further 5 into the observational arm of topical treatments. To reach our target of 140 patients in the RCT arm, we need to recruit 5 patients per month.

We now have 44 centres around the UK open to recruitment, with a further 7 awaiting the necessary approvals before starting.

Invitation letter

Hopefully you have sent the invitation letter out to patients with a previous diagnosis of PG – this was sent to you by email at the time your site became open to recruitment. This was definitely a worthwhile exercise, as we have had several patients come forward as a result of the letter to say they would be interested in taking part in the trial should they have a recurrence of the disease.

If you haven't already done so, please send the letter out! Ask Eleanor to send it to you if you don't have it already!

STOP GAP Star recruiter!

Dr Chris Bower, Consultant Dermatologist at the Royal Devon & Exeter NHS Trust, has now screened 6 patients for the trial and has recruited 4 of these into the RCT arm, which is excellent! Here's how he's done it....



"I'm very pleased to have recruited 4 patients into STOP GAP. At Exeter we have a 'hub and spoke' model community leg ulcer service based around a written protocol: 'Step Forward to Healthy Legs'. The daily service is run by specialist nurses in Tissue Viability based in a community hospital (Franklyn) in the city centre. District nurses run leg ulcer clinics at community hospitals throughout Devon PCT, with support from the Tissue Viability nurses. As a Consultant Dermatologist, I hold a weekly clinic at Franklyn, where patients with recalcitrant ulcers and suspected non-vascular causes of ulceration can be referred. The advantages from this set-up are that patients with leg ulcers are able to get combined specialist Consultant Dermatologist and Specialist Nurse Management in an accessible location. An apparent additional advantage is that the clinic design facilitates entry of patients into clinical trials. As well as STOP GAP, we have recently completed assisting in the VULCAN trial - a 2-centre RCT of silver-donating dressings in the management of venous ulcers"

www.stopgaptrial.co.uk

Don't forget to check the trial website for information and guidance. You will also find useful forms on here in the researchers only sections (username: xxxx, password: xxxx)

Screening patients

Thank you to all of you who fax over your screening logs when requested. As you know, it is really important for all patients who may be eligible for the trial to be listed on the screening log, regardless of whether they are entered into the trial. This is to ensure accurate reporting at the end of the trial and for us to monitor reasons why patients are not eligible for the trial.

It is also important to remember that patients who may not be suitable at the moment, may be eligible in the future – e.g, if a patient is currently taking prednisolone for another medical condition; it may be that the patient may stop the steroid in the future and therefore you may be able to recruit them (if it has been stopped for a month).

Patients already taking the trial drugs

By far the most common reason patients are not eligible for the trial is that they are already taking one of the trial medications, usually prednisolone. Clearly in some cases this is unavoidable. However, by speaking to your dermatology, gastroenterology and rheumatology colleagues and informing them about the trial, it may be that the patient can be referred to you before treatment is commenced. Regularly informing your colleagues is always helpful to boost the profile of the trial!

It is also important to remember that whilst this is a pragmatic trial and clearly if clinically the patient needs to stop the drug, wherever possible they should remain on the randomised treatment. If they do change treatment, they should continue to be followed up in the trial.



Tissue Viability Society

Dr Tony Ormerod, Lead Clinician for the trial, is giving a talk at the Tissue Viability Society Annual Conference due to be held in Telford in April 2010. Eleanor will also be at the conference and will have a stand in order to promote the trial more widely to Tissue Viability Nurses.

GCP reminder

Don't forget to do your GCP training

http://www.ukcrn.org.uk/index/training/courses/governance/gcp_online.html

Investigator meeting



We held a joint STOP GAP & BLISTER Investigator meeting on 25 January 2010 in Nottingham, and we are pleased to say it was a great day! 60 investigators, a mixture of dermatologists & nurses, were able to attend the day and feedback was very positive, with everyone saying that overall the day was 'excellent' or 'very good'. We were lucky to have educational talks by Dr Richard Groves, Head of Clinical Immunology at the St John's Institute, who spoke about the immunology of bullous pemphigoid and Dr Calum Lyon

Consultant Dermatologist at York, who presented cases of pyoderma gangrenosum. Dr Chris Bower & Dr Karen Davies, both Consultant Dermatologists in Devon, gave talks about how they manage the trials from a site's point of view. Slides & other information from the day will be available on the website in the near future.

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

Eleanor Mitchell
Julie Barnes

Trial Manager **0115 8230489 / 07528 377169**
Trial Administrator **0115 8230486**