



STOP GAP Newsletter

Issue 4, November 2010



Thank you to you all for your continuing enthusiasm and effort in making 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

We are currently running at 76% of our target

53 patients have been entered into the RCT with a further 24 into the observational study

Let's push up to 100% - with your help we can do it!



Centre spotlight Aberdeen

Seven patients (4 RCT, 3 observational) have now been recruited at the Aberdeen Royal Infirmary by Dr Fiona Craig and Dr Tony Ormerod. Here Fiona tells us how they have promoted the trial:

Given the relative rarity of pyoderma gangrenosum it is important to try and ensure that investigators in each centre are made aware of as many cases as possible, in order that patients are screened for entry into the trial. Perhaps the most important aspect of this is to ensure that all members of your own department (including other medical staff and nursing staff, particularly those with an interest in leg ulcers) are aware of the trial and refer patients on appropriately. It is also imperative that colleagues are aware not to start systemic treatment before the patients are seen by the investigator.



Our star centres!

- | | |
|------|------------------------|
| 1st | Hull |
| 2nd | Aberdeen |
| 3rd | Exeter |
| =4th | Norwich |
| =5th | Birmingham (Selly Oak) |

BAD Patient Info Leaflet

If you aren't already aware, the B.A.D published a new Patient Information Leaflet about Pyoderma Gangrenosum in June. This can be found at the following website address:

[http://www.bad.org.uk/
site/1396/default.aspx](http://www.bad.org.uk/site/1396/default.aspx)

Here in Aberdeen we have identified a number of cases from in-house referrals from other clinicians or leg ulcer nurses. We have also seen a number of cases referred by our colleagues in plastic surgery and gastroenterology. We have written to colleagues in plastic surgery and gastroenterology and have provided them with contact details for our STOPGAP investigators and our research nurse. It is also important that junior colleagues in dermatology (including registrars, SHOs and GP trainees) are fully aware of the trial as they may be referred inpatients with PG from other departments.

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**

Important reminders re trial documents

- Please remember to initial and date **any** changes that you make to trial documentation
- The trial checklist should be completed on each CRF
- Data query forms (DQF) should be completed, signed and dated and then faxed to 0115 8230515 as soon as possible, in order for our trial database to be up-to-date. The original DQF should be then filed in the patient's trial file.
- Please ensure that **all** boxes on the consent form are **initialled** by the patient (not ticked). The patient should also complete their own name and date at the bottom of the page—you should not do this for them.
- I have recently undertaken a few visits to Sites and reviewed Site Files—it is **really** important that you ensure your Site File is up-to-date. All correspondence sent by myself and the R&D dept should be filed in the appropriate place. You should also make sure that CVs, GCP certificates and evidence of trial training are filed for **all** members of staff working on the trial.

No topical therapy!

There have been several instances from various sites when patients have been given topical therapy, in addition to the systemic therapy they are receiving on the RCT.

Please remember that patients in the RCT should **not** receive topical therapy. They can be prescribed topical therapy up until the point they are randomised, but this should then be stopped.

If you do have patients in the RCT that have been prescribed topicals, you should ensure this is recorded on the CRF where it states 'has the patient taken any other medication which could influence PG'.

Boosting recruitment

You have hopefully now received the checklist regarding ways in which you can try to boost recruitment locally. I hope you have found this helpful. As I said in the accompanying letter, if you have implemented recruitment initiatives locally that have worked and I haven't mentioned, please do get in touch, as it would be nice to share this information with the rest of our sites.

You may also like to consider adding a link to the STOP GAP Trial website on the Dermatology page of your Trust's website (if you have one). The website address is www.stopgaptrial.co.uk.

Please note that we do not have ethical approval to directly advertise to patients (i.e in newspapers etc), but we do have approval to add links to our website in various places.

2011 Investigator meetings

Thank you to those of you who have already responded to the Investigator meeting invitation.

For those of you who haven't yet, in response to feedback from this year's event, we are holding 2 meetings:

- Wednesday 16 February - Newcastle
- Tuesday 8 March — London

The meetings are a great way of networking with fellow STOP GAP investigators and receive up-date training. As previously, we will also be including an educational element to the day and hope to receive CPD points for this. To book a place, please contact Julie Barnes: j.barnes@nottingham.ac.uk or 0115 8230486.

We look forward to seeing you there!