STOP GAP Newsletter

Issue 3, May 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 73% of our target

30 patients have been entered into the RCT with a further 18 into the observational study

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

Our star centres!

1st	Exeter
2nd	Hull
3rd	South London
=4th	Norwich
=4th	Aberdeen
=4th	Nottingham

Trial website

We will soon be adding a new section to the researchers only (username: xxx password: xxxx) section of the website which will include new PG publications you may find of interest. Watch this space!

If you have ideas for other things you would like to see on the website, please let us know!

www.stopgaptrial.co.uk

Centre spotlight

In this edition, Dr Shernaz Walton, Consultant Dermatologist at the Princess Royal Hospital in Hull tells us how her team manage the STOP GAP Trial. They have so far screened 10 patients, recruiting 5 into the trial.

" I am very fortunate to be working as part of an excellent team, consisting of Katherine Ashton (Research Nurse), Angela Oswald (Leg ulcer nurse practitioner) and Deborah Graham (Specialty Doctor). Angela has been involved with 4 leg ulcer trials and runs our leg ulcer clinic both in Dermatology and in the Vascular Surgery department. I have a special interest in Pyoderma Gangrenosum (PG) and in the past have treated this relatively rare condition with different systemic therapies including pulse cyclophosphamide infusions. This study has given me an opportunity to test 2 commonly used treatment modalities and my aim is to develop evidence based pathways to standardise care in different areas of the country.

Katherine and Angela have liaised with the Rheumatology and Gastroenterology nurses, inc. Stoma nurses and the IBD nurse & with their networking have managed to increase recruitment rates in this department. We also have strong links with the community leg ulcer nurses and this helps us to recruit as we also have a very short waiting list in our leg ulcer clinic of 1 week to see their suspected PG patients.

The key to our success is a combination of team working, networking and the continued satisfaction of patients attending our leg ulcer clinic".

Making the all important diagnosis!

When talking to clinicians involved in the trial, many express how difficult it is to make an accurate diagnosis of pyoderma gangrenosum. Dr John English, Consultant Dermatologist at Nottingham University Hospitals NHS Trust, explains what he looks for when making the diagnosis:

"Patients may or may not have an obvious underlying disease such as inflammatory bowel disease, sero-negative rheumatoid arthritis or myleoproliferative disorder. PG can be broadly classified into 3 clinical presentations, all are painful, and unfortunately histology may show non-specific changes.

Ulcerated type: any ulcer that has a violaceous edge, preferably overhanging that is very painful and enlarging, not always rapidly. Usually on the leg.

Pustular type: necrotic pustular lesion(s), enlarging and painful, may be multiple – will have necrotic (violaceous) edge. Any part of the body.

Superficial (vegatitive) type: painful and has violaceous edge and is superficial. Any part of the body"

We would like to try and standardise the diagnosis of PG as far as possible, and would therefore encourage you to use the diagnostic criteria guidance found in the patient file whenever possible.

Wound Care

Fiona Craig, ST5 in Aberdeen & a member of the Trial Management Group talks about wound care:

"In general, participants in the trial should have standard wound care, using locally available dressings and expertise. Most dressings are suitable (e.g. hydrocolloid, hydrogel, soft polymer etc) but we would ask that dressings containing honey should be avoided as should larval therapy. In Aberdeen our standard practice would be for the patient to be seen by one of the dermatology nurses for dressing at the initial clinic visit.

The dermatology nurses can then advise community nurses as to the most suitable combination of dressings and the optimal frequency of dressings changes. Ideally the community nurses should contact the dermatology department if any advised dressings are unavailable so that an alternative can be suggested".

Tissue Viability Society

Eleanor attended the TVS annual conference in April and talked to lots of TV nurses. Lots of community nurses took information about the trial. If you haven't already done so, consider talking to your community TV nurses to promote the trial. If you need any assistance, let us know!

Just a few reminders!

- When sending digital images, please remember to change the file name to SiteNumber_PatientNumber_DateImageTaken_letter A, B, C or D, i.e 001_001_01.05.10_A. You only need to take 4 images on 3 visits (baseline, week 6 & final visit).
- Wherever possible, please keep the patient on their randomised treatment. If you do need to change it, however, you must let us know by completing the top half of the Change of Status CRF in the patient file, and then continue to see the patient for the trial. If you are unsure about what to do, get in touch!
- Please only record definite PG patients on the screening log—if you have not entered them into the trial because you are unsure the diagnosis is PG, you **should not** enter them on the screening log.

Feedback from MHRA inspection

As some of you may be aware, Nottingham University Hospitals NHS Trust (the sponsor of this trial) was inspected by the regulatory authority, the MHRA, in February 2010 and STOP GAP was selected. The following points were noted at the inspection:

Investigator training
It is important that anyone working on the trial is trained in trial procedures. Following the PI's training and/or site initiation, it is the responsibility of the PI to ensure any additional staff are trained before they undertake any trial duties. You should use the Investigator training log which you were previously emailed in order to document this has happened.

The importance of medical notes
It is very important that the patient's involvement in the trial is documented in their medical notes. The trial patient file does not in any way replace the medical notes, and you should continue to complete these as you would normally. We will be circulating a document which clearly outlines what information you should record in the notes. When you receive this, please ensure it is filed in your Site File. It is summarised here:

What you need to write in the medical notes for EVERY trial visit
1. Date of birth & gender
2. Patient's weight
3. Medical history
4. A statement to say the patient is involved in the trial (at the 1st visit only)
5. Informed consent (signed & dated)
6. Complications and/or AEs
7. Date of each visit and who performed the visit
8. Date of the end of a participant's involvement in the trial

The medical notes are considered 'source data' for all of the above items of data.

Original CRF entries
Once you have sent top copies of CRFs in to us, please don't change an entry. Any missing or spurious data will be dealt with by a data query form which we will send to you by email. The top and bottom copies of CRFs should remain identical.

John English, Principal Investigator in Nottingham, was involved in the inspection and gives his thoughts below:

"We prepared as best we could with advice on what to expect and duly turned up at the appointed time like nervous school children summoned to the head teacher's office! The MHRA inspector was very friendly, but extremely thorough. He emphasized that his duty was to make sure we were conducting the study safely and accurately so the results could be relied upon and no patients would come to any unnecessary harm. What did I learn?: Keep good records in the "source data" ie hospital notes and transpose into the CRFs and double check the CRFs before signing off – he found several minor mistakes which I had failed to spot. Don't be anxious of MHRA inspections as it is about patient safety and trial accuracy, which at the end of the day is what we are doing the study for in the first place".

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

Eleanor Mitchell	**Trial Manager**	**0115 8230489 / 07528 377169**
Julie Barnes	**Trial Administrator**	**0115 8230486**