

PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

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PREVENTT News

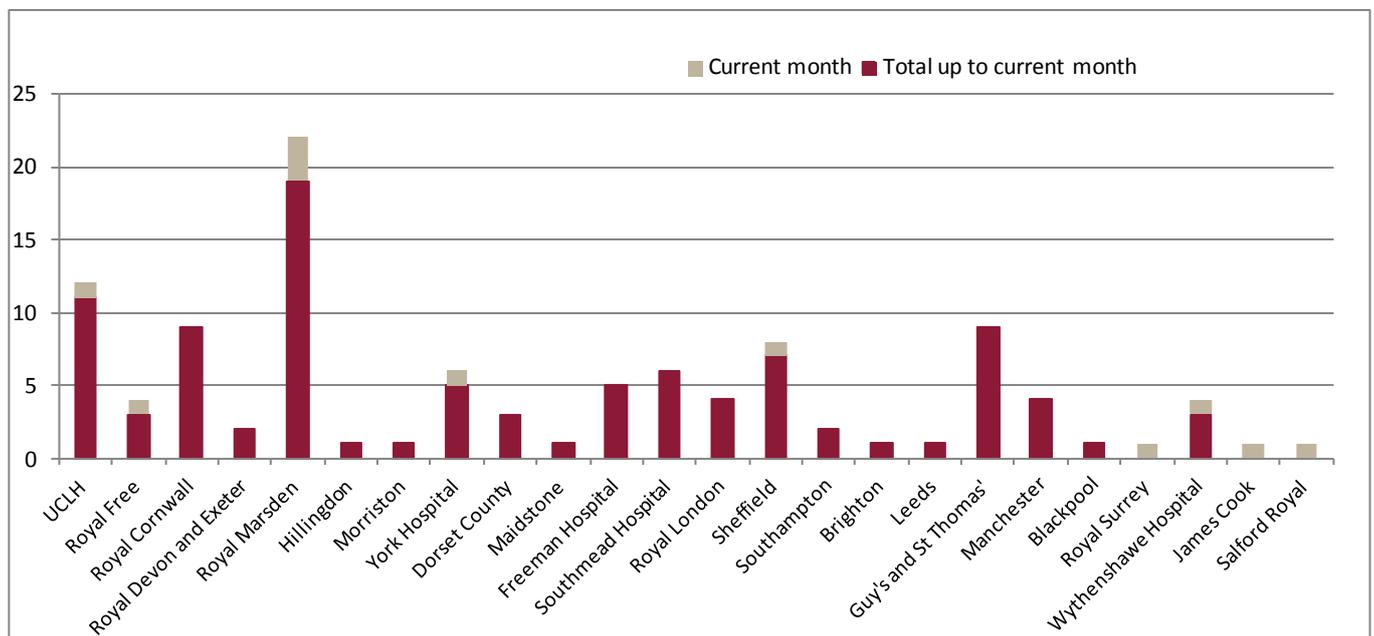
It has been a busy month in the PREVENTT office, especially as during February we recruited patient 100 and had our highest number of randomisations in one day with 4 patients enrolled into the trial. Congratulations to Ravi, Ethel and the team at the Royal Marsden who recruited patient 100 and thank you to all our sites for your continued support for the trial.

Our 28th site, Royal Liverpool has now opened. Welcome to Chris Brearton, Jane Parker and the rest of the team. During 2015, a number of new sites will be joining the trial, increasing the number of sites to 35.

This is a slightly longer newsletter than normal as it includes a summary of the investigator meeting held at the end of January. We hope that you find this information useful for your own local screening and recruitment pathways. If you have any questions or would like any further information about any of the points raised, please get in touch with the PREVENTT CTU.

PREVENTT Recruitment- 109 Patients Randomised

Congratulations to the teams at James Cook (Middlesbrough), Royal Surrey and Salford Royal who all recruited their first patients during February. Over all 11 patients were recruited at 9 different sites. Next month we are aiming to recruit 15 patients so please keep getting in touch with any queries about patient eligibility.



PREVENTT Lucky Number

Congratulations to the Royal Marsden who recruited patient 109 and win the chocolates. The lucky number for March will be **123** as we aim to get our best month for recruitment!

Central Consent Form Monitoring

Remember to send in consent forms for all patients randomised into the trial. These should be sent by email or to our secure fax machine. If you have any questions about this process, please get in touch with Laura Van Dyck (Laura.Vandyck@lshtm.ac.uk).

PREVENTT Investigator Meeting– 29th January 2015

Many thanks to all those of you who were able to attend the meeting at the end of January and ensured that it was such a success. We had representation from 24 sites and it was good to meet so many of you again following the site initiation visits over the past year.

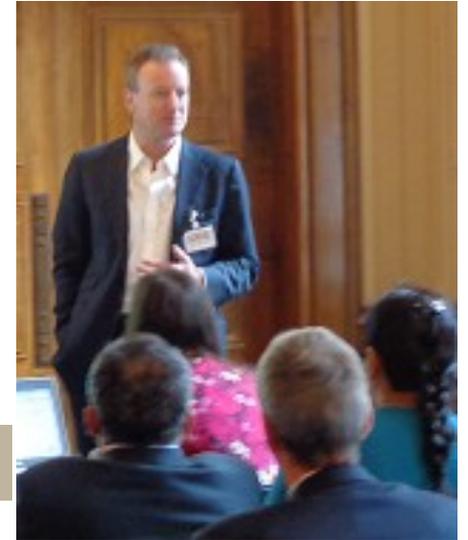
As part of the meeting, we had talks from several different sites to give an overview of recruitment and the different challenges that are involved. Many thanks to Ethel Black, Sumayer Elhanash and Lizzie Roberts for participating in our Q&A session. Our two keynote talks were given by Prof Martin Brown and Dr Charlie Pedlar. Martin Brown is a professor of neurology based at UCL. He has run many stroke trials and gave us his tips for successful recruitment. Charlie Pedlar works at St Mary's and is involved in research looking at the health of endurance athletes.

PREVENTT Q&A– Key Points

During the meeting, time was set aside for a question and answer session. This included a wide range of questions however a few key themes emerged:

- The timing of preassessment appointments has changed at most sites and they are now often too close to the date of surgery to recruit patients into the trial.
- At several sites, it has been difficult to bring patients back following preassessment for randomisation and treatment administration. Therefore it is best if this can be done at a scheduled clinic visit.
- It is therefore more important to try and obtain a FBC earlier in the patient pathway. Under NICE guidance (<http://pathways.nice.org.uk/pathways/preoperative-tests#path=view%3A/pathways/preoperative-tests/preoperative-tests-overview.xml&content=view-index>) this can be clinically justified.
- Possible ways to ensure that a FBC is available include asking the surgeon to take this at an earlier outpatient appointment. Some sites are also exploring the possibility of using point of care testing, for example a HemoCue, to obtain results more quickly.
- The trial is still only open to patients undergoing open surgery however if there are queries regarding other types of surgery, eg laparoscopic assisted surgery, more advice can be provided by the PREVENTT CTU.

A more detailed document with all the Q&As from the meeting is available.



Site Perspectives

Guy's and St Thomas': Lizzie Roberts (Research Nurse)

We recruit patients from our POPS (proactive care of older people undergoing surgery) clinic where all patients over the age of 65 undergoing major surgery are referred for their preassessment. However we still have many of the same issues as other sites, in particular different teams do a FBC at different points in the surgical pathway. Patients are screened from all the major areas, colorectal, upper GI, urology and gynae.

We often complete part of the preassessment appointment with patients. This helps develop a good relationship with the patient and provides an opportunity to discuss the trial.

We also have similar to issues to other sites with the timings of preoperative clinic appointments. Often patients are seen in POPS clinic 5 days before their surgery date and a FBC is not taken at the surgical outpatient clinic prior to referral to POPS.



Royal Marsden: Ethel Black (Research Nurse)

Patients are usually identified from electronic patient records (eg. surgical clinic appointments, theatre lists). All potentially eligible patients are discussed at our weekly team meeting. If a patient is suitable, a doctor either telephones them if there is sufficient time or they are approached on the day of their preassessment appointment. Some patients have been approached, consented and randomised on the same day.

We no longer wait for preassessment to identify patients. It is important to have a blood result available earlier than this and it has been important to keep the profile of the trial high with surgical colleagues. This involves attending regular clinics. Patients undergoing surgery for gynae, colorectal, upper GI and urology are screened and all patients screened are undergoing surgery for cancer.

Wythenshawe: Sumayer Elhanash (PI)

We originally decided to focus on gynae surgery as this has the largest number of open cases within the Trust. Initially, we worked with some key surgeons to get them involved and change the preop pathway. Patients are now brought in for preassessment 4 weeks before their surgery date rather than 2 weeks. So far 3 patients have been recruited since opening to recruitment at the start of October 2014. Our plan is now to increase regular screening to other areas and we continue to send regular reminders to relevant areas of surgery and thank teams for the referrals received so far.

From above: Lizzie Roberts, Ethel Black and Sumayer Elhanash presenting at the Investigator Meeting

PREVENTT– Key Note Speakers

Prof Martin Brown gave an interesting talk on the tips that he has learnt to conducting a successful clinical trial. Although his trials have been in stroke patients, many of the strategies used can be applied to any trial.

- When approaching patients about the trial, become their friend
- Ensure that patients are aware that being part of a trial can bring extra attention and hospital appointments and that this is positive!
- Nursing support is key to ensuring successful recruitment
- Ensure that there are a wide range of sites involved in the trial– more sites equals more patients.

Our final talk of the day was from Dr Charlie Pedlar. Charlie's main area of research is the health of endurance athletes and he has been working with Toby to look at the role of iron deficiency in this particular group. It was interesting to hear about research using a similar drug to PREVENTT in a different setting and in a very different group of individuals!



Prof Martin Brown and Dr Charlie Pedlar presenting at the investigator meeting

And finally...

Remember to send in your travel expenses if you have not done so already! Reasonable second class travel will be reimbursed. The expense form and copies of any receipts can be returned using the envelope provided in the investigator meeting folder to Jo Astarci.

Ben and Toby's Top Tips!

- Getting a screening haemoglobin as early as possible during the pre-operative period is key to success
- Surgical colleagues are key to this – requesting blood tests from surgical outpatients, and not waiting until pre-assessment is a big help
- Consider expanding screening to a broad range of surgical specialities
- Surgical involvement and 'buy-in' really helps, patients like to know that their surgeon supports the trial
- It is important for the PI to be proactive, attending clinics, raising the profile of the trial and calling patients

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