PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

Issue 12
September 2014

PREVENTT News

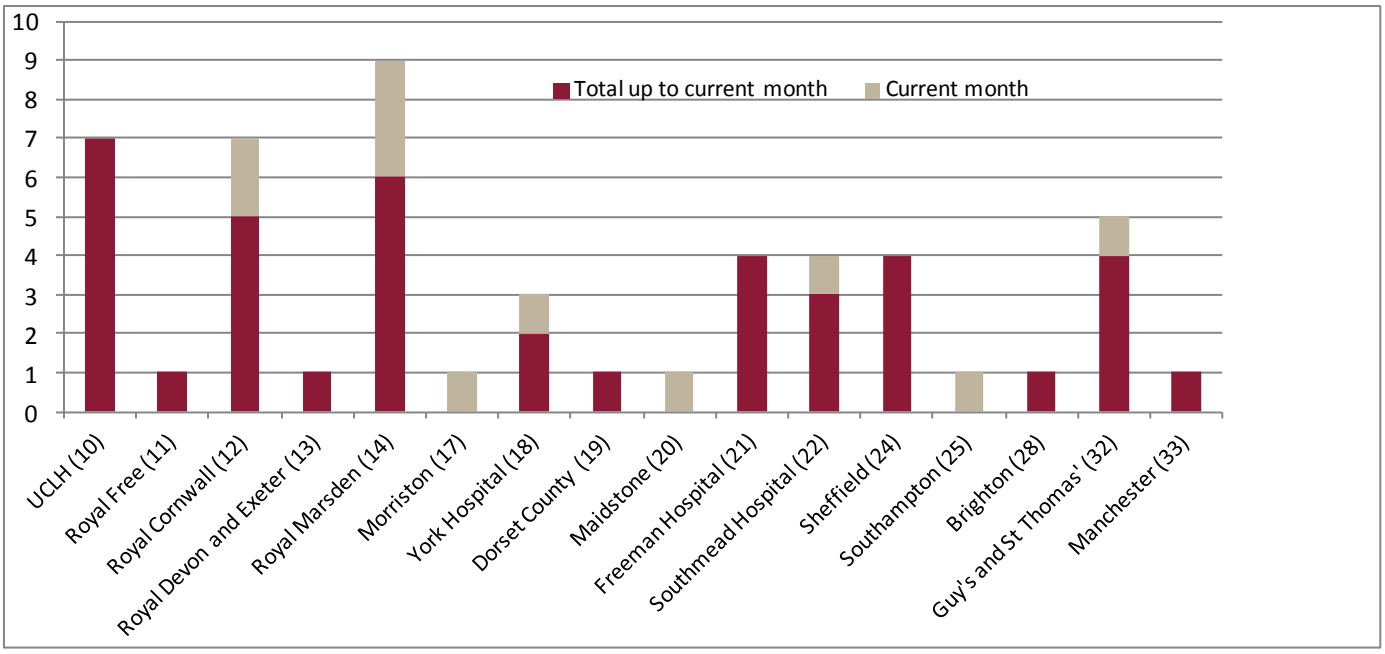
Welcome to the 12th PREVENTT newsletter. We hope that you have all had a good summer.

Over August, set up has continued to progress well at several sites and the 20th PREVENTT site initiation visit was held up in Blackpool at the end of the month. Thank you to Dr Jason Cupitt and the team for their time during the visit. Further site visits have also been arranged for Leeds, Royal Surrey, West Suffolk and Wythenshawe hospitals over September bringing us closer to our target of 30 sites.

As part of our monitoring processes, we have completed the first onsite monitoring visit at UCLH and we are currently monitoring the consent forms for all patients recruited to date. There will be further news about this in the next newsletter once this has been completed.

PREVENTT has now been open to recruitment for 12 months and we are pleased to say that during August we achieved the milestone of 50 patients recruited in the trial. Thank you all for your hard work screening and recruiting patients.

PREVENTT Recruitment– 51 Patients Randomised



This month congratulations go to the teams at Southampton, Maidstone and Morriston hospitals who all recruited their first patients. 16 sites have now recruited at least one patient into the trial which is a great achievement. The top recruiting PREVENTT site during August was the Royal Marsden with three patients randomised. In total 11 patients were randomised across 8 sites.

PREVENTT Data Safety Monitoring Committee

The PREVENTT DSMC will be meeting on 30th September so the AE database and eCRF need to be as complete as possible. This is to allow time for the statistician to analyse the data. Therefore, all outstanding data queries should be completed by the 4th September. If you have any questions about any queries raised, please get in touch with Laura Van Dyck (Laura.Vandyck@lshtm.ac.uk).

Site Profile– Royal Marsden Hospital

PI: Ravi Rao-Baikady
Research Team: Helen Lawrence (Anaesthetist), Maria Koutra (Anaesthetist) and Ethel Black (Research Nurse)

The team at the Royal Marsden are currently the top recruiting PREVENTT site with nine patients. Below, they have summarised the pathway they are using to identify patients.

We are fortunate that staff, and often patients, at our hospital are very familiar with what is involved with performing clinical trials. Eligible PREVENTT patients are identified mainly by looking at surgical outpatient clinic lists, and electronic patient records mean we can quickly see if and when surgery is planned. If the patient appears to be eligible, one of the research team telephones them to tell them about the trial. We post them an invitation letter and PIS, and aim to recruit them when they come for their pre-assessment appointment. We provisionally book a bed in our Clinical Assessment Unit or Medical Day Unit on the day they are coming for pre-assessment so that we can carry out the infusion on the same day, if they consent. This reduces the need for extra hospital visits, which is important for our patients. Good communication between members of the whole team is key to ensuring the process is as smooth as possible.

If you would like to share how you are recruiting into PREVENTT at your site, please get in touch.

Lucky Number!

Starting in October, whichever site randomises the months' lucky number will be the winner of a box of chocolates. Watch this space for updates on the first PREVENTT lucky number!

PREVENTT Delegation Logs

All open PREVENTT sites are being asked to complete a new version of the delegation log. This version of the log will be used for all new PREVENTT sites. When completing this, please consider the following:

- Only unblinded staff can be delegated responsibilities relating to randomisation and trial treatment.
- Signing off adverse events can be delegated to other members of the team, it is only serious adverse events which require PI sign off.

Please get in touch with the PREVENTT CTU if you have any questions.

Patient Withdrawal

Very occasionally patients request to be withdrawn from the PREVENTT trial. It may be due to a number of reasons either personal or clinical.
If they request to be withdrawn then that is the patient's right as they are free to withdraw at any time, without giving a reason and this will not affect their treatment at the hospital.
However, if this happens please establish whether they are happy to be followed up or are requesting no contact at all. Please check with the patient that they are happy for us to use the data collected so far and also check that they would be happy for the nurse to review their notes at 6 months to check for any blood transfusions. If the patient is clear that no information should be collected then please inform the PREVENTT CTU and send a copy of the completed withdrawal form via email or fax.

Contact Information

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