PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

Issue 08
May 2014

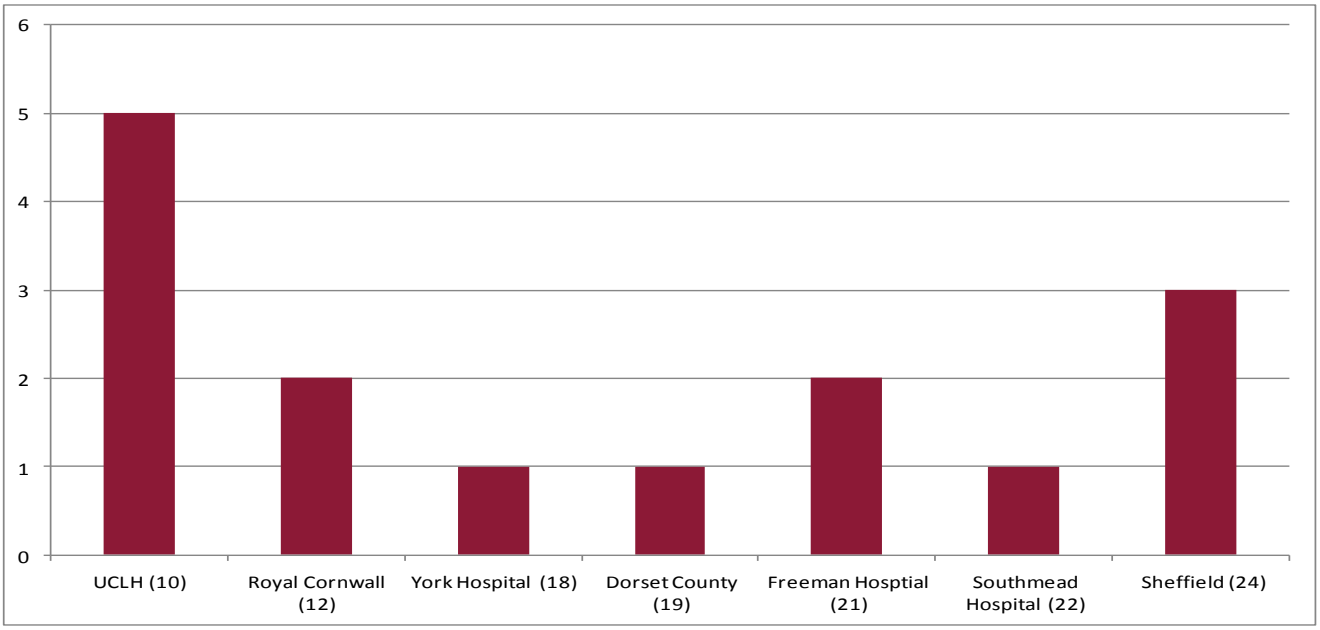
News

Welcome to the 8th issue of the PREVENTT Newsletter. During April, our 13th site, the Royal Marsden opened to recruitment. Thank you to all the staff who attended the site initiation visit. There are already further site initiations arranged for May and the PREVENTT team are looking forward to meeting the research staff at Royal Devon and Exeter, Central Manchester and Morriston Hospitals.

During April, staff at recruiting sites will have received updated copies of the PREVENTT CRF, Unblinding SOP and eCRF SOP. Please take time to look through these. The main changes have been to the process involved in confirming patient eligibility. Eligibility should still be signed off by the PI or another delegated clinician however details of this will now be recorded in the randomisation system. If you have any questions about any of the changes, please get in touch with the PREVENTT CTU.

PREVENTT Recruitment– 15 Patients Randomised!

There are now 13 sites open to recruitment with a further 5 sites expected to open by the end of May. 15 patients have now been recruited into the study and this month congratulations go to Royal Cornwall who have recruited their second patient, Northern General who have recruited their third patient, the team at Southmead Hospital who have recruited their first patient and the team at Freeman Hospital who recruited their first two patients. Seven PREVENTT sites have now recruited into the study and we look forward to our other sites recruiting their first patients soon.



Please continue to screen patients regularly for inclusion into the study. If you have any questions or queries relating to a patient's eligibility, further advice is available from the PREVENTT CTU or in the FAQs on the PREVENTT website.

Contacting Patients

One of the key aspects of recruitment into PREVENTT is to identify patients as early as possible in the pathway. This can be challenging, however contacting patients in advance of scheduled clinic visits is one way that this can be done. The PREVENTT protocol allows patients to be contacted via telephone or using the patient invite letter and sites are encouraged to use both these strategies in recruiting patients.

In particular, please consider the following:

- Initially, patients are often more willing to discuss the study with a doctor.
- It is important to ensure that patients receive the PIS following a telephone call, if they did not receive this beforehand, so they have time to fully consider the study before they attend a clinic appointment.
- It is important to remember that when approaching patients via post or telephone, that you may need to check whether or not they have been told that they will have surgery.

There is some further advice on the potential points that can be raised when contacting patients by telephone available from the PREVENTT CTU.

Frequently Asked Questions:

Q. *In relation to hospital stays, what counts as a day?*

A. Any portion of any day will count as one day. For example, if a patient is admitted in the morning and is discharged 5 hours later, their stay will count as 1 day. If a patient is admitted on one day and discharged the next, their stay will count as 2 days.

Nurses Teleconference

There will be a teleconference for nurses involved in PREVENTT on 8th May at 2pm. The main focus of this call will be on screening and recruiting patients. It will be an opportunity to discuss potential strategies and to share your experiences of the trial so far. It is hoped that this teleconference will also be useful for sites who are currently setting up the trial. Minutes from this meeting will be sent round to nurses at all sites.

If you did not confirm your attendance via the recent doodle poll and you would like to attend, please get in touch with Becky Swinson.

Role of the DSMC

Joanna Dobson is the Independent Statistician for the PREVENTT Data and Safety Monitoring Committee (DSMC). The DSMC is an independent group whose role is to examine the data accumulated during the trial to ensure that it is proceeding as planned and that there are no issues surrounding patient safety. It is the only committee which has access to outcome data broken down by treatment during the trial. The DSMC meets at least annually to review the data. The meeting consists of two parts: an 'open' session where the Trial Manager updates the DSMC on trial progress, and a 'closed' session which involves only the DSMC and the independent statistician who prepares the data for review. After the meeting, the DSMC pass their recommendations for the trial to the Trial Steering Committee. Possible recommendations include to continue the trial as planned, continue with modifications or, in extreme cases, stop the trial.

Contact Information

Website: **http://preventt.lshtm.ac.uk/**

Tel: **+44 (0)20 7927 2071** Fax: **+44 (0)20 7927 2189**

Email: **preventt@lshtm.ac.uk/rebecca.swinson@lshtm.ac.uk**

This project was funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 10/57/67).

NHS National Institute for Health Research

ISRCTN67322816