

PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

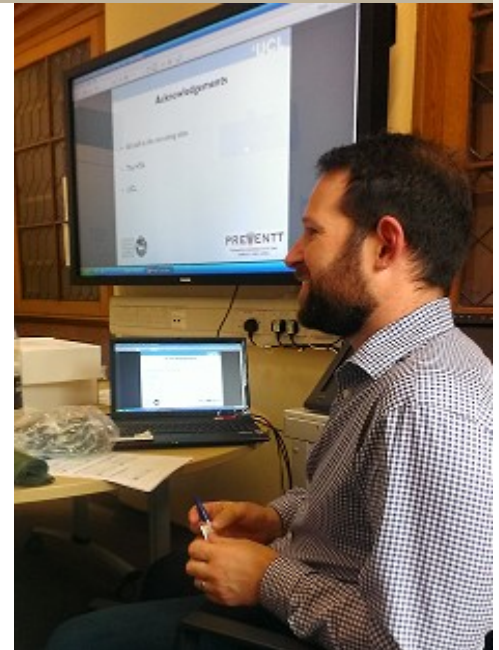
Issue 13
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PREVENTT News

Welcome to the 13th PREVENTT newsletter. It has been another busy month in the PREVENTT office with four site initiations. Welcome to the teams at Wythenshawe, West Suffolk, Royal Surrey and St James' Hospital Leeds. Thank you all for your time at the site visits and we look forward to you recruiting your first patients soon.

The 25th PREVENTT site initiation will be taking place at Royal Liverpool on 6th October. Dr Chris Brearton and Jane Parker have worked to set up PREVENTT over the summer having only been approved by ethics as a site at the start of July. Thanks to this hard work, time from approval to site initiation is 3 months, the quickest of any PREVENTT site.

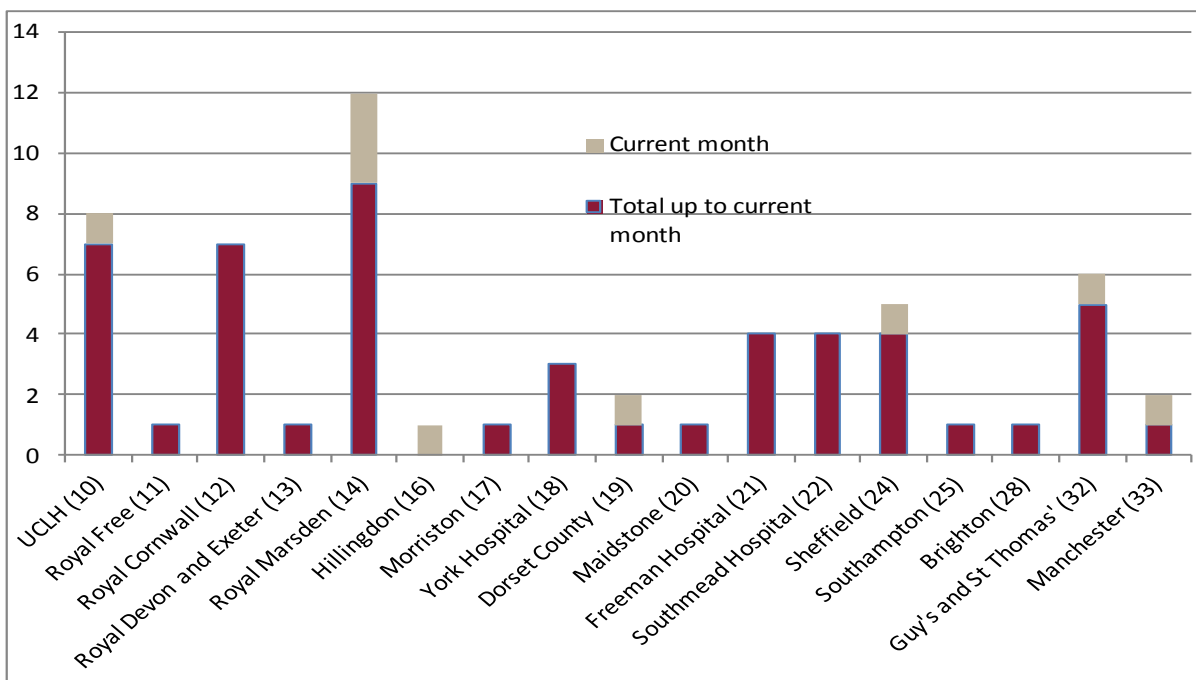
During September, there have also been meetings of the Trial Steering Committee and the Data Safety Monitoring Committee. The Trial Steering Committee have agreed some changes to the protocol and we will be informing sites of these once the new documentation has been finalised.



PREVENTT Research Fellow, Ben Clevenger at the PREVENTT site initiation in Leeds

PREVENTT Recruitment– 60 Patients Randomised

This month congratulations go to the team at Hillingdon who recruited their first patient into the trial. A total of 17 sites have now recruited at least one patient into the trial. Congratulations also go to the team at the Marsden who have recruited 3 patients this month. They are now the first PREVENTT site to have double figures with a total of 12 patients randomised. In total 9 patients were recruited into the trial during September. Thank you all for your hard work.



PREVENTT Consent Forms

Consent forms for all PREVENTT patients should be sent to the PREVENTT CTU for central monitoring. Thank you to all recruiting sites for sending the consent forms for patients recruited to date to us.

The following issues have been raised following monitoring of these consent forms:

- Please ensure that if the PI did not take consent for the patient that they still sign off the form. This can be done at a later date.
- Patients should initial the boxes, these should not be ticked or left blank.

For future patients, please ensure that copies of consent forms are sent to the PREVENTT CTU. These can be sent either to our secure fax or via a secure pdf. Further details can be found in the Consent SOP. If you have any questions about the process, please get in touch with Laura Van Dyck (Laura.Vandyck@lshtm.ac.uk)

Patient Follow Ups

There are now more patients who are approaching their 8 week and 6 month follow ups. It is important to capture as much information as we can at these visits. This includes the patient diaries, quality of life questionnaires and the endpoint data around transfusions. The patient diary will need to be reviewed carefully for details of any hospital admissions.

It is important that patients are aware of the follow up involved in the trial at the time of consent to minimise patient drop outs. These follow up visits should be accommodated where possible alongside routine clinical appointments. If patients are unable to attend clinic for follow up, then this can also be done via phone and post.

If you are having issues with patient follow up visits, do let the PREVENTT office know and we can find ways to capture the data that is needed.

PREVENTT Lucky Number

In the last newsletter, we announced that the PREVENTT lucky number competition would be starting in October. During October, the site who randomises patient **68** will win a box of chocolates. So keep screening patients to be in with a chance of winning!

Nurses Teleconference

Following on from the successful nurses teleconference held in May, a further teleconference will be held at the end of October. Dates for these will be sent round to blinded and unblinded nurses.

The focus of this teleconference will be on screening and consenting patients. However if there are any specific issues that you would like to discuss, please get in touch with Becky Swinson so that they can be added to the agenda.

Frequently Asked Questions

Q. *If during a transfusion, not all of a blood pack is used, does it count as a whole used unit?*

A. Yes. If a blood pack is allocated, delivered and opened, it will count as one unit of blood used no matter how much of the pack is actually used. If a blood pack is allocated and delivered but not opened/used, it is counted as blood wastage and does not count. So any blood given, even a drop, is counted as a transfusion.

Q. *Will it be obvious from the many blood tests whether the patient has received iron or placebo?*

A. Not necessarily. Certain values will be different in the run up to surgery (e.g. Hb differences caused by patients being nil by mouth prior to surgery). Full details of the blinding procedures will be included in the trial treatment SOP. Also the repeat blood samples taken at the 'pre-operative' trial visit are blinded to the centre.

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