PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

Issue 01
September 2013

The PREVENTT Newsletter

Welcome

Welcome to the first PREVENTT newsletter which will be sent out at the beginning of each month. These will replace the monthly e-bulletins.

Since the PREVENTT grant started on 1st September 2012, a lot of progress has been made. A well attended Investigator Meeting was held in May this year where we had some good discussion about the background and logistics of the trial. The Trial Steering Committee and Data Safety and Monitoring Committee have both held their first meetings and the Project Management Group continue to meet regularly.

Recruitment is due to start at hospital sites from September 2013. Our first site, University College Hospital, London have received R&D approval and are now ready to start screening patients. Progress has been made at several other centres with approvals being sought and site agreements being reviewed. Monthly progress on all sites will be included on future newsletters and the PREVENTT team look forward to meeting with you all at up coming site initiations.

PREVENTT Site Update

PREVENTT will involve 20-25 sites and thank you to you all for the work you have already put in to get the trial started at your centre. Below is a list of the sites currently confirmed to participate. If you have any questions about the trial and set up at your centre, please get in touch with the PREVENTT office.

UCLH	Mr James Crosbie	**Freeman Hospital, Newcastle**	Dr Ahmed Chishti
Royal Free Hospital	Dr Susan Mallett	**Southmead Hospital**	Mr Raj Persad
Royal Cornwall	Dr Catherine Ralph	**Royal London Hospital**	Dr Shubha Allard
Royal Devon and Exeter	Mr John Thompson	**Northern General, Sheffield**	Dr Sumayer Sanghera
Royal Marsden	Dr Ravishankar Raobaikady	**Southampton General Hospital**	Dr Mark Edwards
Queen Elizabeth Hospital, King's Lynn	Mr Paul Cullen	**University Hospital of North Staffordshire**	Dr Charles Baker
Hillingdon Hospital	Dr Cheryl Messer	**Bristol Royal Infirmary**	Dr Claudia Paoloni
Morriston Hospital	Dr Dafydd Thomas	**Royal Sussex County Hospital Brighton**	Dr Robert Kong
York Hospital	Dr Jonathan Wilson	**Royal Bournemouth Hospital**	Dr Martin Clark
Dorset County Hospital	Dr Matthew Hough	**St James' Hospital, Leeds**	Dr Alwyn Kotze
Maidstone Hospital	Dr Andrew Taylor	**Guy's and St Thomas' NHS Trust**	Dr Jugdeep Dhesi

POMS Training

Hopefully, all blinded nurses involved in the trial have now received details of the dates for the Post-operative Morbidity Survey (POMS) Training. The information collected as part of the POMS will form part of our secondary endpoints. One or two nurses from all our participating centres will need to receive this training before recruitment can start at their centre.

POMS Training will be taking place on the following dates at LSHTM in central London:
19th September from 2-4pm
2nd October from 2-4pm
24th October from 2-4pm.

If you haven't done so already, please return your booking form either by fax (020 7927 2189) or email (preventt@lshtm.ac.uk) to the PREVENTT coordinating centre.

Frequently Asked Question:

Q. Laparoscopic surgery patients have been excluded, does this exclusion count for any conversion operations or robotic operations? And why are you excluding laparoscopic procedures?

A. *Yes, this exclusion includes conversion and robotic operations. We are currently excluding laparoscopic patients because overall laparoscopic surgery has a lower blood transfusion rate, and if we included such patients then we would need to recruit a higher number. The Trial Steering Committee has agreed to review this should there be problems with recruitment, but at present we are not including laparoscopic patients.*

Meet the PREVENTT Team

This Month: Becky Swinson, PREVENTT Assistant Trial Manager

I recently joined LSHTM to work as the Assistant Trial Manager for PREVENTT and will be the main point of contact for sites during site set up and recruitment. Prior to this I worked at St George's University performing research in Stroke and at Bristol Oncology Centre co-ordinating cancer clinical trials. When I'm not in work I enjoy running and eating.

Eligibility

Inclusion:

- Patients aged 18 years and above
- Patients undergoing elective major open abdominal surgery
- Screening haemoglobin 9.0-12.0g/dl
- Randomisation and administration of study infusion 14 -42 days before planned operation

Exclusion:

- Patients undergoing laparoscopic surgery
- Body weight under 50kg
- Known history of acquired iron overload, or family history of haemochromatosis or thalassemia or TSAT >50%
- Known reason for anaemia
- Known hypersensitivity to Ferinject®
- Temperature >37.5°C or patient on non-prophylactic antibiotics
- Chronic liver disease and/or screening ALT or AST above 3 times the upper limit of the normal range
- Received erythropoietin, i.v. iron therapy or blood transfusion in previous 12 weeks
- Immunosuppresive therapy or renal dialysis (current or planned)
- Pregnancy or lactation
- Inability to fully comprehend and/or perform study procedures in the investigator's opinion
- Patient involvement in another IMP trial within the previous four weeks, prior to randomisation or involvement in another IMP trial following randomisation that may impact on the results of the PREVENTT trial

Contact Information

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