PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

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News

Welcome to the second PREVENTT newsletter. It has been a busy month in the PREVENTT office as hospital set up progresses at a number of sites. During September, the second site initiation took place at the Royal Cornwall Hospital in Truro. It was good to meet Cathy Ralph and the team there and we look forward to their first recruits.

Several other centres have their site visits arranged during October and we hope to have many more visits in the diary over the next couple of months. The e-CRF is also in the final stages of testing and will be ready for sites to use during the next month.

PREVENTT Site Update

	Site Name	Update
10	UCLH	Open to recruitment
11	Royal Free Hospital	Local R&D application started
12	Royal Cornwall	Open to recruitment
13	Royal Devon and Exeter	Local R&D application started
14	Royal Marsden	Local R&D application started
15	QEH King's Lynn	Local R&D application started
16	Hillingdon Hospital	Local R&D approval received– site initiation on 02/10/2013
17	Morriston Hospital	Reviewing Trial Documentation
18	York Hospital	Local R&D application started
19	Dorset County Hospital	Conditional local R&D approval received
20	Maidstone Hospital	Local R&D application submitted 21/08/13– site initiation 03/10/2013
21	Freeman Hospital, Newcastle	Local R&D application started
22	Southmead Hospital	Reviewing Trial Documentation
23	Royal London Hospital	Local R&D application started
24	Northern General, Sheffield	Local R&D application started
25	Southampton General Hospital	Local R&D application started
27	Bristol Royal Infirmary	Local R&D application started
29	Royal Sussex County Hospital	Local R&D application started
29	Royal Bournemouth Hospital	Reviewing Trial Documentation
30	St James' Hospital, Leeds	Reviewing Trial Documentation
32	Guy's and St Thomas'	Reviewing Trial Documentation

If you have any questions about the trial and set up at your centre, please get in touch with the PREVENTT office.

POMS Training

The second of our POMS training sessions was held at the London School of Hygiene and Tropical Medicine during September. Thank you to our POMS trainers, Debbie Smyth and Paula Meale. It was an interesting session and alongside the training, there was an opportunity for more general discussion about the trial and how set up is progressing at the different centres.

If you have not already booked onto training there are still places for the session on the 24th October from 2-4pm which can be booked by returning the POMS booking form to the PREVENTT office by fax or email.

Meet the PREVENTT Team

This Month: Laura Van Dyck, PREVENTT Trial Manager/Data Manager

Laura has worked in clinical trials for over 14 years, and since returning to LSHTM she worked on a pediatric intensive care trial (CHiP) prior to starting work on PREVENTT.
Before LSHTM she worked on a variety of cancer trials at the Medical Research Council CTU, including ICON7 and STAMPDE.
Outside of work Laura loves to travel and is an avid Saints football fan.

Frequently Asked Questions:

Q. *Will patients need any separate screening bloods as the patient needs to be consented before any trial specific samples can be taken?*

A. No, there are no extra bloods needed for screening the patient. Any blood sample results which are taken as part of routine care can be used for inclusion into the trial as long as it is within 4 weeks of randomisation.

Q. *The screening bloods include TSATs. Could patients still be included who do not have this done routinely?*

A. Part of the exclusion criteria is to exclude patients with iron overload, which is defined as a patient having a **known** TSAT > 50%. (Therefore, if a TSAT test has not been done already, this test isn't needed as part of the screening).

Updated MHRA Guidance

The MHRA have issued additional guidance for the administration for intravenous iron.

As part of this, sites will need to ensure that they monitor patients closely both during and then after the treatment administration for at least 30 minutes for signs of hypersensitivity reactions. However, as there will be baseline data to collect for patients and the patient diaries and quality of life questionnaires to complete, this is a good opportunity to ensure that these are completed.

They have also advised that patients with severe asthma and allergies should only be given intravenous iron if the benefits outweigh the risk as they have an increased risk of hypersensitive reactions. This is already advised in the PREVENTT protocol however we are now asking sites to ensure that these patient are not recruited and the exclusion criteria will be amended to reflect this.

If you have any further questions about Ferinject, further details can be found in the Summary of Product Characteristics or on the MHRA website.

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