PREVENTT

Preoperative intravenous iron to treat anaemia in major surgery

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News

Welcome to the first PREVENTT Newsletter for 2014. Following on from our first patient at the start of January, the team at York Hospital recruited the second PREVENTT patient at the end of the month. Combined with the approvals that have been received for amendment 2, it has been a positive start to the new year! The changes made as part of the amendment are designed to improve the patient pathway and to help sites to screen patients more easily. They also reduce the number of hospital visits for patients. Further details of the changes can be found on page 2.

At the start of February, the PREVENTT team will be welcoming our new Research Fellow, Ben Clevenger. Ben will be helping with recruitment at some of our centres and will be responsible for answering medical queries so many of you will get to know him over the coming months.

PREVENTT Site Update

At the start of January the ninth PREVENTT site, Southampton General, opened to screening and recruitment. Screening is now well underway at several centres and the PREVENTT team will be working with closely with all open sites to increase recruitment in the coming months.

Site initiations have been arranged at a further two centres and we are looking forward to meeting the teams at Southmead Hospital and Guy's and St Thomas' during February and March. A further 5 sites have also received approval to participate in the trial and, over the coming months, set up will commence at these centres.

	Site Name	Update
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
17	Morriston Hospital	Reviewing Trial Documentation
21	Freeman Hospital, Newcastle	Local R&D application started
22	Southmead Hospital	Local R&D approval received– site initiation on 03/02/2014
23	Royal London Hospital	Local R&D application started
27	Bristol Royal Infirmary	Local R&D application started– site initiation on 03/12/2013
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– site initiation on 03/03/2014
36	Blackpool	Reviewing Trial Documentation
37	West Suffolk	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.

Amendment 2

Staff at all centres should now have received copies of the newly approved documentation, which includes a new version of the protocol, patient information sheet, consent form and patient invitation letter.

The main changes to the protocol are outlined below:

- Randomisation and administration of the study infusion can now take place 10-42 days before the planned surgery date.
- Patients no longer need to attend clinic for the pre-operative visit 14 days post treatment administration. Assessments from this timepoint will take place when the patient is admitted for surgery or will be self-completed by the patient at home.
- Changes to the exclusion criteria to reflect the guidance issued by the MHRA about intravenous iron use.
- Changes to the recruitment and consent process to allow centres to telephone potential patients in advance of clinic appointments and to allow patient's to consent earlier than 24 hours if they wish to.

The aim of these changes is to help the study visits and intervention to fit more easily into the patient pathway.

If you have any questions or queries about any of the changes to the protocol, please get in touch with the PREVENTT office to discuss them further.

Frequently Asked Question

Q: *How is severe asthma or severe allergy defined?*

A: Hospital inpatient admission with a diagnosis of severe asthma or severe allergy for treatment in the past year

Meet the PREVENTT Team

This Month– Tim Collier, Trial Statistician

Hello, my name is Tim Collier and I'm the statistician for the PREVENTT trial (please read on!) I know statisticians can be a bit dull but medical statistics and clinical trials are great areas to work in and most medical statisticians I know aren't too boring. As the PREVENTT statistician I've been involved right from the beginning, helping with the trial design and working out how many patients we need to recruit. One of the great things about working on a trial is that you learn lots from the people you are collaborating with - and PREVENTT has been no exception. We've got a great team. My principal involvement in PREVENTT will be when all the patients have been recruited, treated and followed up and I can get on with analysing the data to see if the treatment is effective. So come on get those patients recruited!

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