

The ERIC-PPCI Newsletter

News

A warm welcome to the November issue of the newsletter.

October was an excellent month with the first ERIC-PPCI patient recruited at Cumberland Infirmary on the 28th October 2015! Congratulations to the PI, Dr Madhusudhan Varma and the clinical and R&D team at Carlisle.

It is an exciting time for the trial and means we are ahead of our schedule as recruitment was not due to start until February 2016.

A second site initiation was also held at Barts Heart Centre and further site initiations are scheduled for November at John Radcliffe Hospital in Oxford and Basildon Hospital in Essex. If you would like to arrange a site initiation visit in the next couple of months please refer to the article on the second page of this newsletter which outlines what to expect and how to prepare for it.

The website <http://ericppci.lshtm.ac.uk/> is now live and is a great resource for information on the trial, FAQs and documentation.

First patient recruited!

Site Update

Open sites:

Cumberland Infirmary, Carlisle and Barts Heart Centre, London. Barts is expected to be open to recruitment in the next few weeks.

Site Initiations planned:

John Radcliffe Hospital, Oxford (17th November 2015), Basildon Hospital, Essex (19th November 2015)

Contracts fully executed and site initiations in the next few months:

Northern General Hospital in Sheffield, Blackpool Victoria Hospital and Royal Free Hospital in London.

All other sites are currently reviewing documentation.

Device Training Video

The CTU team and Manish Ramlall, research fellow at Barts have been working on a video to help demonstrate the trial equipment and intervention and shows how simple the device is to operate. This will be available on the website in the next few weeks.

FAQs—ECGs



Do we need to take copies of the ECGs?

Yes, two ECGs for each patient are required, at baseline and post-PPCI. The baseline ECG will generally be an ambulance tracing. The post-PPCI ECG will be the one taken closest to 90 mins after the PPCI.

How should these be saved and sent to back to the CTU?

The ECGs should be photocopied as they are taken. Photocopies are easier to read than scans or faxed copies. The scanned ECGs should be emailed to ericppci@LSHTM.ac.uk in batches. Please name the files as Patient ID visit, e.g.

- 14001_baseline.PDF
- 14001_postPPCI.PDF

Does a 12 lead ECG need to be taken?

No a rhythm print out would suffice.

Site Initiations

With site initiations being planned at a number of hospitals, here is a quick guide on what to expect and how to plan for an ERIC-PPCI site initiation visit (SIV).

When can a site initiation take place?

Site initiations will be arranged to take place shortly after you have received local R&D approval. These can be booked in advance if you are expecting to receive R&D approval within the next month.

Who should attend?

At least the **PI**, main **blinded research nurse** and a member from the **unblinded team** should attend the meeting, though sites are encouraged to invite as many people as possible that may be involved in the trial.

From the trial management side either Prof. Rajesh Kharbanda or Dr Manish Ramlall will be present, along with a member from the CTU, this will usually be Richard Evans.

What happens at the site initiation and how long will it last?

A short presentation will be given followed by a demonstration of the intervention and randomisation website. There is also additional training on study procedures for research nurses.

In total the site initiation should take approximately two and a half hours, depending on questions.

Is any equipment provided?

The following equipment will be provided:

- | | |
|---------------------|---------------------|
| • Trial Site File | • Intervention Pack |
| • 1 x Active device | • 1 x Sham device |
| • 5 x large cuffs | • 5 x small cuffs |
| • 10 x medium cuffs | • 1 x Manual Sphyg |



The equipment provided is quite bulky so it is best to plan ahead where the devices and cuffs will be stored. The devices must remain plugged in and it is recommended that they are plugged in at least a day before you will start recruiting patients to ensure they are charged.

When can we begin recruitment?

Recruitment at a site can begin once the site initiation has been conducted and the site agreement, delegation log and unblinded training log have been completed and received at the CTU.

The CTU data managers, Matt and Steve, will then generate the randomisation accounts and send links to the randomisation website for the specified site staff. eCRF access will be arranged after the first patient is randomised. Paper CRFs will be provided at the site initiation as part of the site file.

If you have any questions regarding the site initiation or would like to book one please contact the ERIC-PPCI CTU at ericppci@LSHTM.ac.uk.

Contact us at the ERIC-PPCI clinical trial unit

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