Issue 8—March 2016

The ERIC-PPCI Newsletter

News

Welcome to the March newsletter, Spring seems to be in the air!

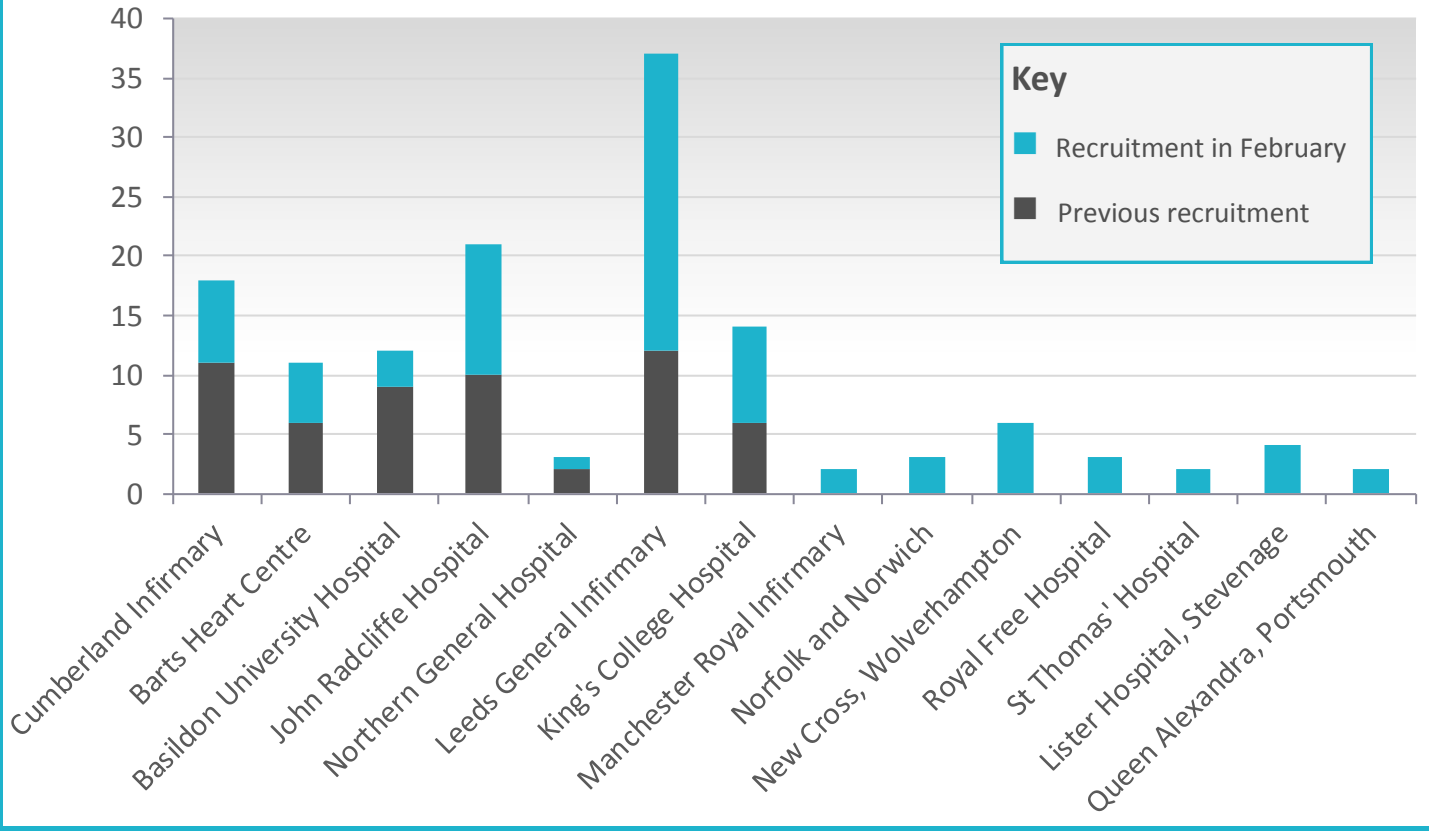
February has been another extraordinary month, the response to the trial has been fantastic. 82 patients were recruited. Site initiations have been held in five sites; Victoria Hospital in Blackpool, Lister Hospital in Stevenage, Papworth Hospital, Queen Alexandra Hospital in Portsmouth and St Thomas' in London. Seventeen sites are now open.

There are now fourteen sites actively recruiting, seven of these recruited their first patients in February. Many thanks and congratulations to the teams at Leeds, Oxford, King's, Carlisle, Wolverhampton and Barts who all recruited more than 5 patients.

During March there are three site initiations planned, at Bournemouth, Brighton and Coventry, and we look forward to having them on board.

138 Patients Recruited

Recruitment Summary



Re-supply of cuffs

The CTU will try to anticipate when a site will need a re-supply of blood pressure cuffs and send replacements, however if you running low of any size in particular please request more by emailing Richard Evans or Rebecca Chu at ericppci@lshtm.ac.uk with as much notice as possible.

ERIC-PPCI Lucky Number

As recruitment has continued to do so well there will be a prize for whichever site recruits the **200th** patient to ERIC-PPCI this month. **Good luck!**

Leeds celebrate ERIC-PPCI's 100th patient

February's lucky number was won by Leeds General Infirmary, who recruited ERIC-PPCI's 100th patient. Leeds have got off to an incredible start with 37 patients already recruited so it was great that they won the lucky number chocolates. Many thanks to the team there led by PI Professor John Greenwood, (from left to right:) Kathryn Somers, Natalie Burtonwood, Arvind Krishnamurthy, Michelle Anderson and Charlotte Harland.

CTU Easter Closure

This Easter the CTU will be closed from Friday 25th March to Tuesday 29th March inclusive. If you have any urgent clinical queries during that time please contact Derek Hausenloy d.hausenloy@ucl.ac.uk and Manish Ramlall mrmanish45@yahoo.co.uk. The CTU will be back up and running on Wednesday 30th March.

Additionally a list of FAQs can be found on the trial website: ericppci@lshtm.ac.uk

ECG Reminder

Please remember to email scans of the ECGs for all patients recruited to ericppci@lshtm.ac.uk

When sending your scans please label them either **Pre-PPCI** or **Post-PPCI** and add the study ID number. Please ensure that you remove all identifiable data. We only require 2 ECGs per patient.

The pre-PPCI ECG may be one taken in the ambulance or on admission.
The post-PPCI ECG should be the one taken closest to 90 minutes after PPCI.

Please do not hesitate to get in contact if you have any questions regarding ECGs.

ERIC-PPCI at Cumberland Infirmary, Carlisle

Cumberland Infirmary *in Carlisle have made a brilliant start on ERIC-PPCI and were the first site to recruit to the trial in October last year. The research nurse leading on the trial there is* ***Chris Relph*** *who has kindly answered some questions on how ERIC-PPCI is being run there.*

Who assesses eligibility of the patients?

Initially we started with the Cardiologists but an item for discussion at our next meeting is to consider the PPCI co-ordinators to take on more responsibility for the assessment of STEMI patients for participation in the trial.

Who takes verbal assent?

The Cardiologists take the verbal assent and get the patients to sign the shortened consent form at the same time as they consent the patient for PPCI. When the assent is done by the consultants the patients seem to be far more receptive to it.

Who randomises and performs the intervention?

At Carlisle we have always aimed to have two trained staff who are able to randomise: Cardiac Physiologists and/or our Heart Centre Staff Nurses (who rotate in and out of the labs). Training for randomisation was initially undertaken by key core of staff but this has now been rolled out to PCI Cath-Lab Nurses and PPCI Co-ordinators. The same team member then puts the cuff on the patient's arm.

Where are the devices/cuffs stored?

Devices and several of each sized cuffs are stored in the Cath Lab so that they are immediately available when needed. Additional cuffs are stored within the store room on the unit. Stock levels of each size are monitored by and are re-ordered through Rebecca Chu. The cuffs arrived by courier within 24-48 hours.

How do you ensure that there is access to a computer for online randomisation?

One of the Cardiac Physiologists arranged for desktop icons to be placed on a laptop and PC in the Cath Lab, on a PC outside and on the PC in the pre-assessment bay – ensuring that the randomisation site can be accessed from anywhere.

How are you working to ensure the intervention is started as soon as possible?

We're looking to involve our PPCI Nurse Co-ordinators who are responsible for calling the team after assessing the patient first, we see potential to start ERIC-PPCI earlier with them involved.

It has been trial and error, but we feel that once a member of staff has randomised a couple of patients, they see that the whole process can be done very easily. I spoke to Dr Varma (PI) and Jeremy Hodierne (Cardiac Tech) about this and we all feel that 20 minutes should be plenty of time if the tasks are delegated to those that are in a position to carry them out promptly. In addition, each member of the unblinded team will do their second patient in half the time of their first. Jeremy's experience is that multitasking becomes easy after a few patients, for example randomising the patient while the equipment in the Cath Lab boots up, it just becomes part of their role.

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ERIC-PPCI at Cumberland Infirmary, Carlisle *continued*

Our set up works well but it has shown us when and where the extra input is needed and at Carlisle it is out of hours – after considering the door to needle process it showed us that having the PPCI Co-ordinators involved could be of benefit. Staff from all roles are pushing the study now.

What are the procedures for informing relevant research staff of a new recruited patient?

Once a patient has been randomised the Research Staff receives an email to confirm this, automatically from Sealed Envelope. I previously worked in CCU as a staff nurse alongside many of the staff involved in the trial and they have my contact number. They all know that I am happy to be contacted directly regarding any issues or queries about ERIC-PPCI. This is something that I am comfortable with, although I know that this wouldn't necessarily work for all centres and we are currently looking into alternate methods.

How will you make sure patients are consented before discharge?

This is the relatively easy stage of the trial – The Research staff screen the Cardiology wards daily in our hospital for other studies anyway.

The Research team member checks on the condition of the patient shortly after their admission. We then make contact with them after around 24 hours, if they are ok. The CCU nurses give the patients the PIS so that when we approach them they have already had time to consider the information and think of any questions.

One issue that has arisen is when a patient was transferred to Tertiary centre (Freeman Rd) before full consent was obtained, were currently looking at approaching the patient on their follow up appointments with our Cardiologists but Richard, Steve, Matt and Manish at the study centre have all been very helpful with this along with many other queries we've came across.

Starting trial treatment—the Leeds experience

To ensure that the RIC stimuli is most effective it is essential that in as many cases as possible at least two cycles of the trial treatment are complete prior to the onset of reperfusion. For sites with short door to balloon times this can present a challenge. ***Michelle Anderson*** *who is one of the unblinded team at* ***Leeds General Infirmary*** *has described the methods used at Leeds to ensure this happens.*

I am always in recovery prior to patient arrival. I will have spoken to whoever is doing the procedure to make them aware. I get as much info from the ambulance referral as possible, which includes symptom onset time, location of infarct, amount of ST elevation and the leads, and past medical history so you can see if a patient will be suitable.

I will have the patient details already entered on to the randomisation system from the information in the referral.

Once I have the verbal agreement I simply randomise and I have the devices and cuffs there ready.

The consent process is the 1st thing we do with any primary and this is done in the recovery area prior to being taken to the lab. The study is also mentioned first so it's not the last thing to be done, once consent is done, its then the study and the lab staff complete their checklists etc, load with tablets so you have a bit of time there to get the cuff on. We also have a research reg that we can ring and he will come down so we are not waiting for the consultant if they are delayed in another lab.

Contact us at the ERIC-PPCI clinical trial unit

Website: http://ericppci.lshtm.ac.uk

Tel: +44 (0)20 7927 2665 Fax: +44 (0)20 7927 2189

Email: ericppci@lshtm.ac.uk / richard.evans@lshtm.ac.uk

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