Issue 10—May 2016

The ERIC-PPCI Newsletter

News

Welcome to the May newsletter. April has been an excellent and busy month for ERIC-PPCI. Recruitment has continued to be phenomenal with 78 patients from 15 sites. The highest recruiting centres this month are Leeds General Infirmary, with 21 and John Radcliffe in Oxford, Queen Alexandra in Portsmouth and Cumberland Infirmary in Carlisle with 8 patients. It is great to see recruitment spread across so many sites.

The 21st site initiation visit was held at Royal Stoke University Hospital, a warm welcome to Dr Rob Butler and the team.

Three more site initiations are planned in the coming months at Birmingham Heartlands, Kettering General and Hammersmith Hospital and we look forward to having these centres on board.

In other news, a substantial amendment for the trial was approved on the 13th April. There have been some minor changes to the protocol and to the patient information and a version control document will be sent out this month to ensure that all sites are using the current versions. For some sites this will aid recruitment as the need for the PCI operator and PI to be blinded has been removed. Please contact us if you have any questions about how the amendment affects you.

304 Patients Recruited!

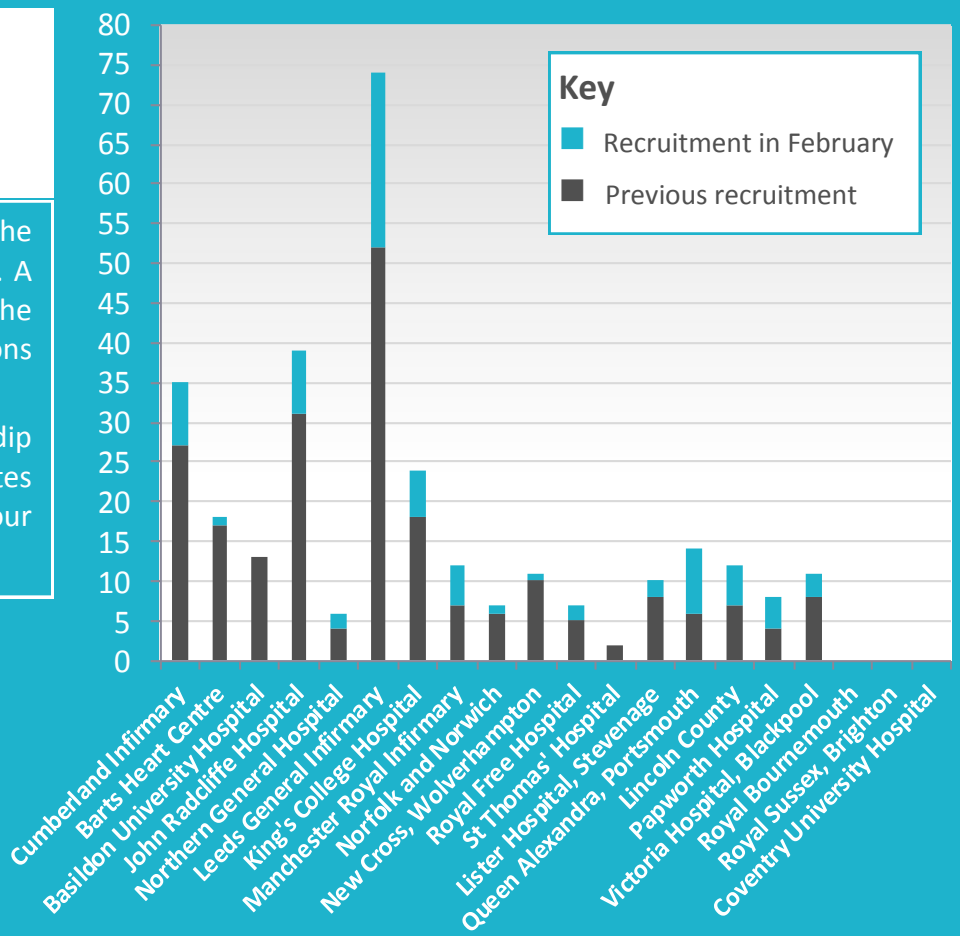
Recruitment summary

Lucky Dip:

Congratulations to the Royal Free Hospital!

Congratulations to Royal Free, the winner of the lucky dip for April. A box of chocolates will be on the way to you shortly. Congratulations for all your hard work.

We will be drawing a lucky dip winner for May from those sites who recruit a patient, so get your recruiting hats on!



Data Tips

Q. What is meant by time of admission on the eCRF?

A. This is the 'door time' i.e. the time the patient arrives at the hospital.

HRA Update

You may be aware that the NHS Health Research Authority (HRA) have changed the way local approvals are processed and there is a new process for NHS sites in England. The new process, which came into effect on the 31st March 2016, replaces the need for local approvals at each individual participating organisation and hopefully will streamline the approval process.

The ERIC-PPCI HRA application will be submitted in early May. Once we have approval we will be contacting all sites and any sites that are waiting to be set up will now follow the new HRA site level process.

If you have any questions regarding the HRA approval process or how this may affect set up at your site please email ericppci@lshtm.ac.uk

Staff Profile: Dan Hetherington

My name is Dan Hetherington, I started in April as a Trials Assistant within the Clinical Trials Unit in the Med Stats Department of the London School of Hygiene & Tropical Medicine (LSHTM).

I first joined LSHTM in September 2012 working in a similar role. My job involves me sending out trial materials, amending documents, booking couriers and any other ad hoc admin duties. In my spare time I like to travel, cycle, and am a huge foodie. I look forward to working with you all.

Withdrawals and Consent Issues

In the past few months this trial has moved forward very quickly, and we are now over 15% of the way to the overall recruitment target. One issue that has come up over this time has been patients not wishing to participate in the trial when they regain capacity after the PPCI. Thankfully this is rare however there are some steps that can be taken to ensure that the wishes of the patient are fully taken into consideration.

If a patient does not want to continue in the trial it may be that they are happy to allow their data to be used. Please consider the following steps;

1. A patient may be willing for their data to be used but does not want to be followed up on the telephone or attend clinic appointments. In that case the follow up can be gathered remotely, using their NHS number, hospital records or through their GP. In this case the consent form would need to be fully signed and a note made locally not to follow up the patient.
2. A patient may be happy for the data already collected to be used, but no further data to be gathered. In this case a consent form would still need to be fully signed and an email should be sent to Matt Dodd and Steven Robertson in order to formally withdraw the patient.
3. A patient may wish to have all of their data removed, in which case there is no need for the patient to sign anything. The eCRF consent page should be marked as 'No' giving a reason and an email should be sent to Matt Dodd and Steven Robertson in order to formally withdraw the patient.

As follow up is so minimal it is hoped that refusals will be very low, and offering option 1 may help to make sure we can gather data on patients even if they personally have no further involvement in the trial.

Contact us at the ERIC-PPCI clinical trial unit

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