The ERIC-PPCI Newsletter

News

A warm welcome to the first edition of the ERIC-PPCI newsletter. These will be sent out to all of the participating sites and anyone else contributing to ERIC-PPCI. This replaces the e-bulletins you may have received in the past few months. If you would like to receive printed copies then please contact the team overleaf.

Ethics approval was given on the 22nd June 2015 by the London-Harrow Research Ethics Committee. Site setup will now proceed and it is hoped that recruitment will begin as soon as possible. The CTU will be in touch regarding site set-up once we have the documentation in place. The trial has also been accepted onto the CRN portfolio.

Participating Sites

27 sites have now confirmed that they will participate in ERIC-PPCI. If your site does not appear in the list below this may be because a feasibility form has not yet been received. There are a maximum number of 30 sites, so to avoid disappointment please ensure that your feasibility form is completed and sent in to ericppci@LSHTM.ac.uk.

Trial Launch



The trial launch will be held on the 9th September 2015 at the Wellcome Collection <u>http://wellcomecollection.org/</u>. There will be time after the meeting to explore their free exhibitions.

Two people who will be involved in the trial from each site are invited to attend. Lunch, snacks and tea/coffee will be provided and travel expenses (standard class) will be reimbursed. Please keep all receipts.

There will be talks on the background of the trial and current progress. The focus of the trial launch however will be on the protocol and the practicalities of running the trial. This is where your input and feedback will be very valuable to help us make this trial a success.

Many of you have already booked a place at the meeting, but if you have yet to confirm or wish to hear more about the meeting please email Rebecca Chu <u>rebecca.chu@LSHTM.ac.uk</u>.

- 10 Barts Heart Centre, London
- **11** Royal Bournemouth Hospital
- **12** Leeds General Infirmary
- **13** Lister Hospital, Stevenage
- 14 Norfolk and Norwich University Hospital
- **15** William Harvey Hospital, Ashford
- **16** University Hospital Southampton
- **17** University Hospital Coventry
- **18** Royal Sussex Hospital, Brighton
- **19** Northern General Hospital, Sheffield
- **20** Kettering General Hospital
- **21** Harefield Hospital, Middlesex
- 22 King's College Hospital
- 23 New Cross Hospital, Wolverhampton
- 24 Royal Derby Hospital
- 25 Royal Stoke University Hospital
- 26 Bristol Royal Infirmary
- **27** Papworth Hospital, Cambridge
- **28** Basildon University Hospital
- **29** Birmingham City Hospital
- 30 Hammersmith Hospital, London
- **31** Birmingham Heartlands Hospital
- 32 John Radcliffe Hospital, Oxford
- 33 Queen Alexandra Hospital, Portsmouth
- 34 North Cumbria University Hospital, Carlisle
- **35** Lincoln County Hospital
- 36 Morriston Hospital, Swansea

CellAegis AutoRIC Devices



The trial intervention will be delivered using CellAegis AutoRIC devices. These devices deliver a full four-cycle RIC protocol at the touch of a button. Two of these devices will be supplied to each centre, one to deliver the RIC protocol and another to deliver the sham protocol.

The device works with disposable single-use applicator cuffs. A selection of sizes will be provided at the site initiation and further supplies will be sent upon request.

The devices need to be charged between uses, so space needs to be set aside for two charging cradles.

The devices are on loan to the CTU so please consider where these will be stored for security and easy access.

For more details on the devices please contact <u>ericppci@LSHTM.ac.uk</u>.

Intention to treat (ITT)

ERIC-PPCI will be analysed using an intention to treat method. An ITT analysis means that patients are analysed in the groups to which they were randomised irrespective of whether the allocated treatment was carried out or not, or was incomplete. So if a patient only has part of the allocated treatment or if the intervention was not carried out, they will be still be included on the basis that the randomised allocation was carried out. This method of analysis is used widely in many trials and offers a more pragmatic approach. This approach is less likely to lead to bias and more closely reflects the impact of treatment as it would apply in clinical practice by recognising that not all patients will comply with treatment policy.

It is also important that even if the patients do not complete the allocated intervention they should still remain within the trial and be followed up as normal. The only reason patients should not be followed up is if they specifically request to be withdrawn from the trial but it is expected that this would apply to very few patients, if any. If in any doubt then please contact the ERIC-PPCI clinical trials unit for further advice if required. In this section we would like to introduce various contributing members of the trial team, whether at the sites or part of the management group. As this is the first newsletter it seems only fair for the trial manager to go first.

Profiles: Richard Evans

I am the trial manager and the main point of contact for ERIC-PPCI.

I have worked here at the London School of Hygiene and Tropical Medicine Clinical Trials Unit for four years, and some of you may already know me from the ERICCA or REVIVED trials. Before that I was involved in breast cancer studies here at LSHTM and worked for 6 years at Imperial College as a research coordinator on studies looking at the vasculature of the retina.

I look forward to meeting many of you on site initiations and speaking to you over the course of the trial. My number can be found below in the contact information section and I am always very happy to talk over any aspects of the trial.

If you would like to contribute to a profile in the future please get in touch.

Contact us at the ERIC-PPCI clinical trial unit

Website: http://ericppci.lshtm.ac.ukTel: +44 (0)20 7927 2665Fax: +44 (0)20 7927 2189Email: ericppci@lshtm.ac.uk/ richard.evans@lshtm.ac.uk

NCT02342522