

The ERIC-PPCI Newsletter

News

Hopefully you have all had a lovely break over the past few weeks and are feeling refreshed and recharged for the next few months. Unfortunately summer seems to be over!

All study wide approvals are now complete. All sites have been sent an email with instructions for beginning the local set-up process and documentation is being prepared.

Do not forget the trial launch is coming up on the 9th September. It promises to be an excellent day with over 70 people confirmed as attending. The Wellcome Collection is the venue, and the meeting will start at 10am,



with registration from 9:30am and lunch at 12:30pm. The meeting is due to finish at 4pm and the galleries are open until 6pm so there is a chance to view their excellent exhibitions. Please remember to keep your travel receipts in order to be reimbursed (standard class only). If you would like to attend but have not yet confirmed then please get in touch with Rebecca Chu as soon as possible at rebecca.chu@LSHTM.ac.uk, as there are very limited spaces left.

We look forward to seeing you there!

Participating Sites—one place remaining

29 sites have now confirmed that they will participate in ERIC-PPCI. There are a maximum number of 30 sites, and once this is reached any further sites will be added to a waiting list. If your site does not appear in the list below and you would still like to participate please get in touch as soon as possible at ericppci@LSHTM.ac.uk.

10	Barts Heart Centre, London	26	Bristol Royal Infirmary
11	Royal Bournemouth Hospital	27	Papworth Hospital, Cambridge
12	Leeds General Infirmary	28	Basildon University Hospital
13	Lister Hospital, Stevenage	29	Birmingham City Hospital
14	Norfolk and Norwich University Hospital	30	Hammersmith Hospital, London
15	William Harvey Hospital, Ashford	31	Birmingham Heartlands Hospital
16	University Hospital Southampton	32	John Radcliffe Hospital, Oxford
17	University Hospital Coventry	33	Queen Alexandra Hospital, Portsmouth
18	Royal Sussex Hospital, Brighton	34	North Cumbria University Hospital, Carlisle
19	Northern General Hospital, Sheffield	35	Lincoln County Hospital
20	Kettering General Hospital	36	Morrison Hospital, Swansea
22	King's College Hospital, London	37	Blackpool Victoria Hospital
23	New Cross Hospital, Wolverhampton	38	Royal Free Hospital, London
24	Royal Derby Hospital	39	St Thomas' Hospital, London
25	Royal Stoke University Hospital		

CONDI 2 Collaboration



The ERIC-PPCI trial will be conducted in collaboration with the Effect of RIC on Clinical Outcomes in STEMI Patients Undergoing pPCI (CONDI2) trial (NCT01857414). Prof Hans Erik Bøtker (Aarhus University, Denmark), is the Chief Investigator. CONDI 2 will randomise 2300 patients in Denmark, Spain and Serbia. Recruitment is going very well with 855 patients randomised so far.

The CONDI 2 trial started in November 2013 in Central Jutland, Denmark. In June 2014 the trial opened in the principality of Asturias, Spain. Since then Northern Jutland joined in August 2014 and Southern Jutland in February 2015. The Capital region of Denmark is expected to join in Autumn 2015, followed by Serbia.

The patient pathway for patients with STEMI in Denmark is slightly different to the UK, with longer transit times to fewer, central, PPCI centres. For this reason consent, randomisation and the RIC procedure is carried out in the ambulance prior to the patient being admitted to hospital.

The results of ERIC-PPCI and CONDI 2 will be combined in order to maximise power to assess the impact of RIPC on clinical endpoints. The trials have been very closely aligned as a result. The inclusion and exclusion criteria and endpoints are exactly the same for both trials. While both trials will have their own Trial Steering Committee (TSC) to respond to local issues a combined TSC will be convened for any issues that affect both trials. There are also combined Data Safety Monitoring and Event Validation Committees.

Data Safety Monitoring Committee

As mentioned above, there is a combined CONDI 2 / ERIC-PPCI independent Data Safety Monitoring Committee (DSMC) which will look at combined data for both trials. The first meeting is planned to take place in the next few months.

The role of the DSMC is to review the accumulating trial data for CONDI 2 / ERIC-PPCI and advise the TSC of both trials on the future management of the trials. The DSMC will review combined endpoint and safety data to determine whether there are any unforeseen effects of the RIC intervention.

The chair is Professor Colin Berry, an interventional cardiologist and cardiology research lead at Golden Jubilee Hospital. He is joined by Tom Meade, Emeritus Professor of Epidemiology at London School of Hygiene and Tropical Medicine, and by Dr Andrew Copas an unblinded statistician from the Medical Research Council, London. Danish and Spanish members of the DSMC are to be confirmed shortly. Jenny Nicholas (ERIC-PPCI) and Jakob Hjort (CONDI 2) will provide statistical support to the DSMC.

Profile: Jenny Nicholas

Dr Jennifer Nicholas is a medical statistician who joined London School of Hygiene and Tropical Medicine in January 2012. Jenny is responsible for producing the reports on the trial data and progress for the ERIC-PPCI Data Monitoring Committee. Jenny has previously been the trial statistician for the REPAIR and ERICCA trials.

Before joining LSHTM, Jenny worked at King's College London where her



research has included design and analysis of clinical trials as well as projects examining the use of epilepsy and diabetes medications and adverse drug reactions.

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