Issue 16— November 2016

### News

Welcome to the November edition of the ERIC-PPCI Newsletter. October 2016 was an eventful month! On the 17th October the trial reached a huge milestone when the 1000th patient was randomised by Queen Alexandra Hospital, Portsmouth. Our first patient was recruited on the 23rd October 2015, meaning ERIC-PPCI has recruited more than half of the total sample size of 2000 patients in under a year. This is a fantastic achievement that everyone involved with the trial should be very proud of.

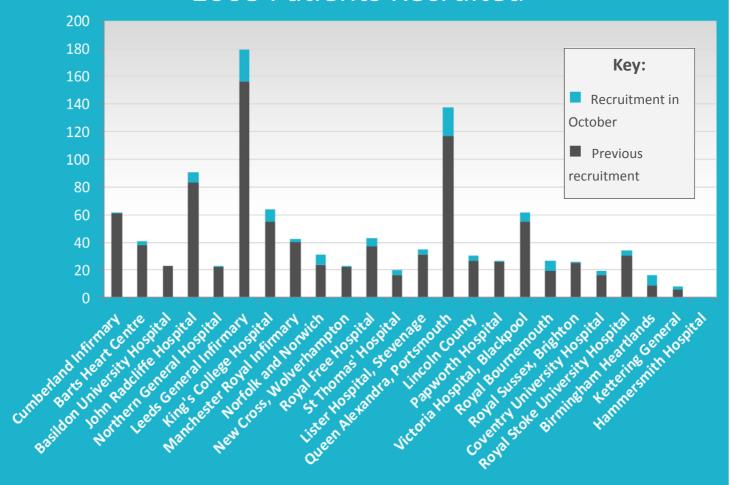
24 sites have been opened to recruitment over the course of that year, and 23 of these are actively recruiting. A further two sites are close to opening, a site initiation was held on the 1st November at Bristol Royal Infirmary and another is planned at William Harvey Hospital in Ashford on the 18th November.

This month's top recruiting sites are Leeds General Infirmary with 23, Queen Alexandra with 21 and Kings College Hospital with 9 patients. Nine additional sites recruited above their recruitment target. Thank you once again for your continued support and hard work.

Over the past few weeks there has been some discussion here at the ERIC-PPCI CTU about ensuring the newsletters are fresh and jam-packed with the latest updates and trial successes. From next month an e bulletin will be sent out every month with a recruitment update, and a full newsletter will be sent out every 3 months.

### Recruitment Update

# 1068 Patients Recruited



## Blackpool Victoria Hospital



Here at Blackpool Victoria Hospital we have thoroughly embraced the ERIC-PPCI clinical trial. Since opening to recruitment in March this year we have randomised 57 patients and indeed 47 of these patients have given informed consent. We feel the success of delivering this study is twofold.

Firstly we have an excellent research team which is truly supported by our Allied Health professionals within the cath lab. Secondly we are a cardiac tertiary centre and receive patients from several other hospitals therefore serving a large geographical area.

We are an extremely research active hospital who strive to offer our patients the opportunity to take part in clinical trials as an extra treatment option. We feel that the ERIC-PPCI trial is an excellent clinical trial to offer to our patients and I believe the high intake suggests our patients agree.

### **ERIC-LIVER**

Derek Hausenloy, the CI for the ERIC-PPCI trial, has just started recruiting to a new remote ischaemic conditioning (RIC) study in Singapore in the setting of liver resection surgery.

<u>Effect of Remote Ischaemic pre</u>Conditioning on liver injury in patients undergoing major LIVER resection surgery: The ERIC-LIVER trial

**Background**: In addition to protecting the heart, limb RIC may also protect other vital organs at risk of acute ischaemia/repefusion injury such as the kidney and liver. Liver resection has improved health outcomes in patients with hepatocellular carcinoma (HCC) in Singapore and worldwide. However, due to acute ischaemia/reperfusion injury (IRI) to the liver at the time of surgery, patients still experience significant morbidity and mortality. Therefore, novel therapies are required to protect the liver against acute IRI during major partial hepatectomy. RIC using transient limb ischaemia/reperfusion has been shown to protect the liver in experimental animal studies. In the ERIC-LIVER trial we investigate whether RIC can reduce liver injury and preserve liver function in patients with HCC undergoing major partial hepatectomy.

**Hypothesis:** RIC will reduce liver injury and preserve liver function in patients with HCC undergoing major partial hepatectomy.

**Methodology:** 50 patients with HCC undergoing major partial hepatectomy will be randomised to receive either RIC (four-5 minute arm cuff inflations/deflations) or sham control (four-5 minute arm cuff simulated inflations/deflations) after induction of anesthesia and prior to surgical incision. The primary endpoint of the study will be acute liver injury assessed by serum transaminases measured at 24 hours post-resection. Secondary endpoints will include liver function in subset of patients (N=24, assessed by indocyanine green [ICG] clearance measured at 24 hours post-resection), incidence of liver failure, episodes of confirmed sepsis, acute kidney injury, intensive care unit and hospital stay, and quality of life.

**Expected outcomes:** If we can demonstrate that RIC reduces liver injury and preserves liver function in patients with HCC undergoing major partial hepatectomy there is the potential to improve health outcomes in this patient group.

#### Contact us at the ERIC-PPCI clinical trial unit

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