

Welcome to the December edition of the ERIC-PPCI Newsletter. November has been a very successful month for ERIC-PPCI with **148** randomisations. Even more importantly all 25 active sites recruited a patient. Thank you!

This month's top recruiting sites are Leeds General Infirmary with 34 (a new record), Queen Alexandra in Portsmouth with 15 and Cumberland Infirmary in Carlisle with 10 patients randomised. A big thank you also to Birmingham Heartlands, Royal Free, John Radcliffe, King's College and Lister Hospital who all at least doubled their recruitment target for the month. Hammersmith Hospital and Bristol Royal Infirmary recruited their first patients. Very well done to the team in Bristol as the SIV was only held on the 1st November.

A Merry Christmas and a Happy New Year from the ERIC-PPCI management team.

## 1216 Patients Recruited

## Intention to treat

ERIC-PPCI will be analysed on an intention to treat (ITT) basis. Due to the emergency setting in ERIC-PPCI a number of patients have been entered into the trial that upon further evaluation do not match the eligibility criteria. These patients should be consented and followed up as usual however it is understood that this is perhaps not what nurses expect. For those who would like further information then there is more included in the book 'Clinical Trials: A Practical Guide to Design, Analysis and Reporting' by Duolao Wang and Ameet Bakhai.

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 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 trial treatment 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 The only reason patients should not be followed up is if they specifically request to be withdrawn from the trial but it is expected that this would apply to very few patients, if any.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 CTU for further advice.

## Christmas Closure—22nd December to 2nd January (inclusive)

London School of Hygiene and Tropical Medicine will be closed from Thursday 22nd Dec to Monday 2nd January, which means that there will be no ERIC-PPCI CTU cover on those days. If you have an urgent clinical query over this time please email **d.hausenloy@ucl.ac.uk** and **mrmanish45@yahoo.co.uk**.