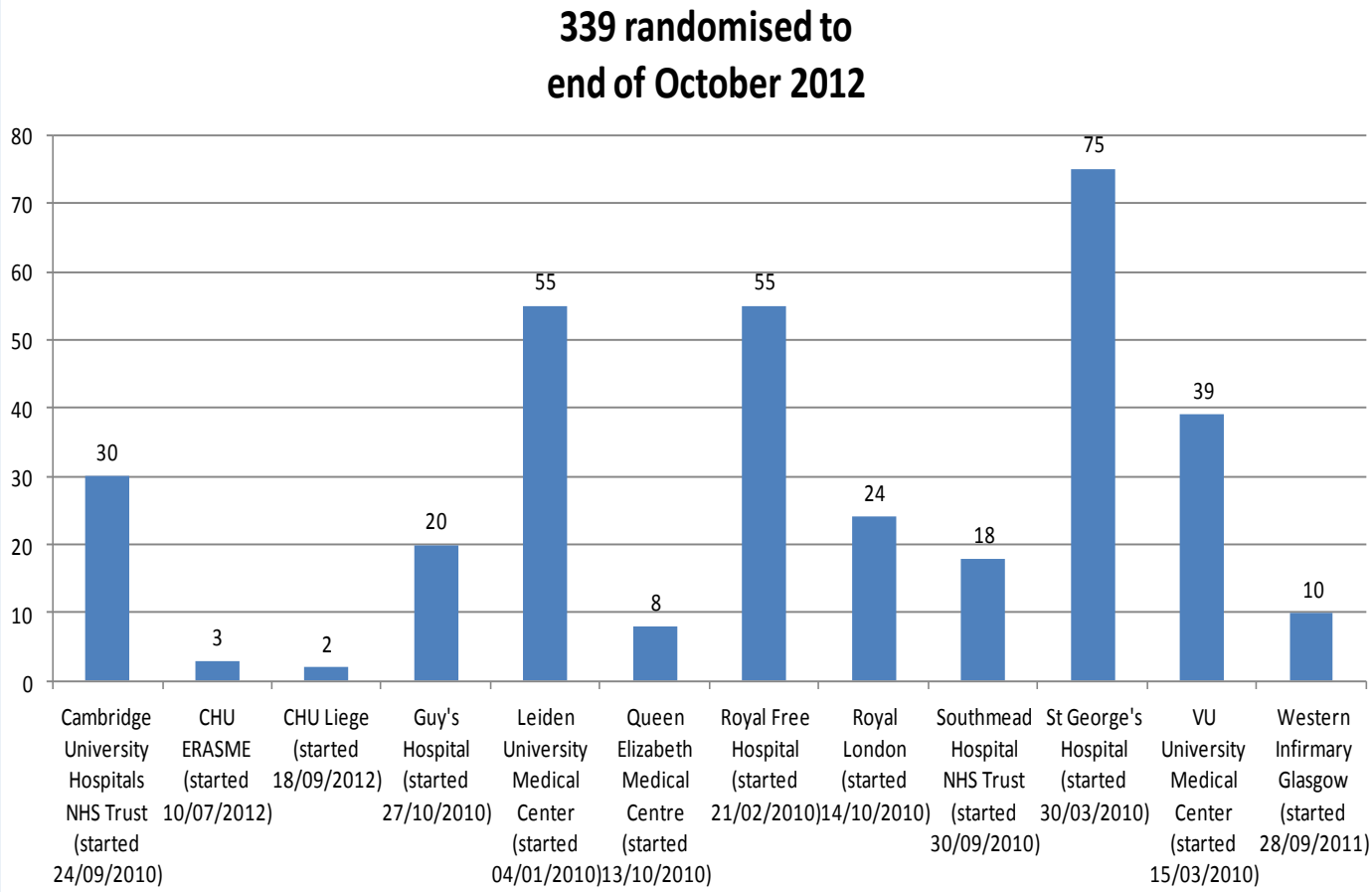
REPAIR Trial Newsletter

REPAIR
Renal Protection Against Ischaemia Reperfusion in Transplantation

Issue 32 November 2012

Recruitment update



October has been another excellent month for recruitment with **16** pairs recruited. Seven out of the eleven actively recruiting centres randomised at least one pair in October and ten out of eleven have randomised at least once since the beginning of September. This is great news and we hope to maintain this momentum to the end of the recruitment period.

Our plan is to keep to the trial deadlines but to allow the Belgian/French sites to recruit for a few months into 2013. This will help recruitment and give more encouragement for these sites to get more involved (rather than recruit for just a few months), and so perhaps obviate any slow-down towards the end of the year. It will shorten the time available to clean/analyse the data but, since the extra number will be small, this will not cause too many problems. So what we propose is an extension to recruitment but not to the time needed to complete the trial. Of course all other sites can continue to recruit during this extended period.

We are waiting on a reply from the funders with regard to this proposal.

Frequently Asked Questions

Question: When should the interventions be carried out?

Answer: The first wave of preconditioning is activated immediately the intervention is applied and lasts for around 4 hours. For this reason it is important that the intervention on the day of transplantation is applied as close as possible to the time of surgery, as typically the operation lasts in the order of 4 hours.

The first intervention should be carried out 24 hours before surgery (plus or minus 2 hours). This allows the second wave of preconditioning, which is activated at around 24 hours after the intervention, to also take effect by the time of the operation.

Despite our best efforts, this may be difficult to ensure in all cases. If the intervention occurs outside the time limits specified above, the patients should still be included in the study. If it is known in advance that there will be a timing issue with a particular pair, again they should not be excluded from the study for this reason. The time of the intervention is documented, and we also ask that the time of induction of anaesthetic (donor and recipient), the clamp time (donor) and reperfusion time (recipient) are recorded. This will enable us to analyse these results. If you have any questions about this please call or email the REPAIR office.

November activity

November is going to be a busy month for REPAIR. The Trial Steering Committee (TSC) are meeting on Monday 12th November and the Data Monitoring Committee (DMC) are meeting on Friday 16th November.

Many thanks to everyone who has responded to the requests for iohexol samples to be returned in time to be analysed for the DMC meeting, and also to Kristin for collecting these from some of the centres!

Please remember that the iohexol samples are required for the 1 year primary outcome. Therefore it is very important that patients are aware of this at the time of consent and reminded regularly from discharge until it is time for the 1 year follow up. This way they are less likely to refuse to come in for the test.

There have also been a number of data related queries sent out recently so many thanks for continuing to respond to these.

Eligibility

Inclusion criteria

- Patients undergoing living donor transplantation
- Patients aged 18 years and above

Exclusion criteria

- Patients on ATP-sensitive potassium channel opening or blocking drugs
- Patients on ciclosporin
- Patients with a known iodine sensitivity (who cannot undergo iohexol clearance studies)
- Patients with ABO incompatibility
- Any patient requiring HLA antibody removal therapy

Please ensure these criteria are checked and confirm patient is eligible **before** completing the randomisation process

Contact details

Tel: 020 7927 2473 **Fax: 020 7927 2189**

Email: repair@lshtm.ac.uk **Web:** http://repair.lshtm.ac.uk/