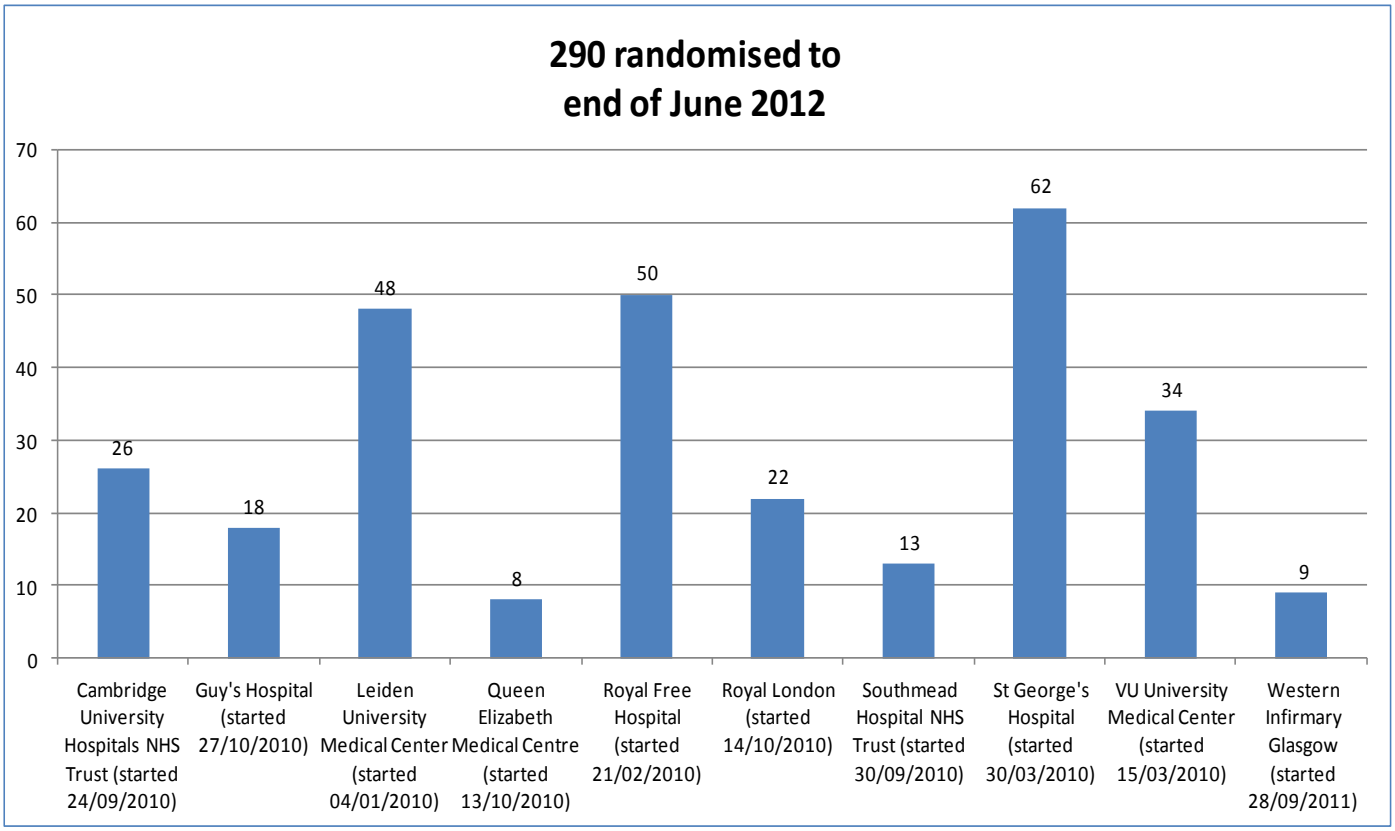
REPAIR Trial Newsletter

REPAIR
Renal Protection Against Ischaemia Reperfusion in Transplantation

Issue 28, July 2012

Recruitment update



Feedback from the Data Monitoring Committee (DMC)

The Data Monitoring Committee (DMC) discussed the trial in January 2012, this was their fifth review of the data. At that time there were no safety issues or concerns and they were happy for the trial to continue. The January DMC had expected to review the primary end point (GFR at 1 year measured using Iohexol clearance) but due to a problem with storage of blood samples at the Royal Free Hospital, only a limited number of results were available. The DMC agreed to meet again by teleconference on 1st June 2012 to review the end point data. The freezer situation has now been rectified, as most of you are aware, and a big thank you to all of you who transferred your samples over to London.

The DMC were satisfied with their review and plan to meet again on 5th October. Again they highlighted the need for continued recruitment and acquiring high quality complete data, but congratulated the Steering Committee on the progress to date.

If you can continue to transfer your samples over to us, that is very helpful. Please contact the REPAIR office to arrange this.

Site initiation visit Belgium

On Thursday 24th May, Rosey and Kristin were lucky to have a trip to Brussels to do site initiation and training for the sites over there who have agreed to take part in the REPAIR trial. So far there are 4 hospitals in Belgium who are hoping to recruit. They are in Brussels, Liege, Antwerp and Gent and each of these sites were represented at the meeting.

Kristin presented background to the trial and progress so far and then demonstrated the intervention on Annick Massart who is the PI at Brussels. Rosey demonstrated the randomisation website.

Ethics approval has been taken forward on behalf of all the sites by Annick in Brussels and we hope to have approval very soon.

Lille in France have also expressed an interest in taking part in REPAIR and are moving forward with ethics approval. We would like to thank Annick and her team for all their hospitality (and excellent cake selection!) and look forward to the first patients being randomised soon.

Set up costs and per patient payments

Please don't forget to send in your invoices for the set up costs and per patient payments. There is a total of £4000 to claim once you have recruited your first 10 pairs and we have received all the baseline data. There is also a payment of £420 for each pair recruited into the trial. This is divided up between baseline data received and 1 year being completed (Iohexol). It is important to send in invoices at least quarterly to us.

The invoices should be made payable to UCL and sent directly to Research Finance Administrator, Research Services, University College London, Gower Street, London WC1E 6BT. If you require further information then please do not hesitate to contact the REPAIR office or refer to your clinical trial site agreement.

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

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