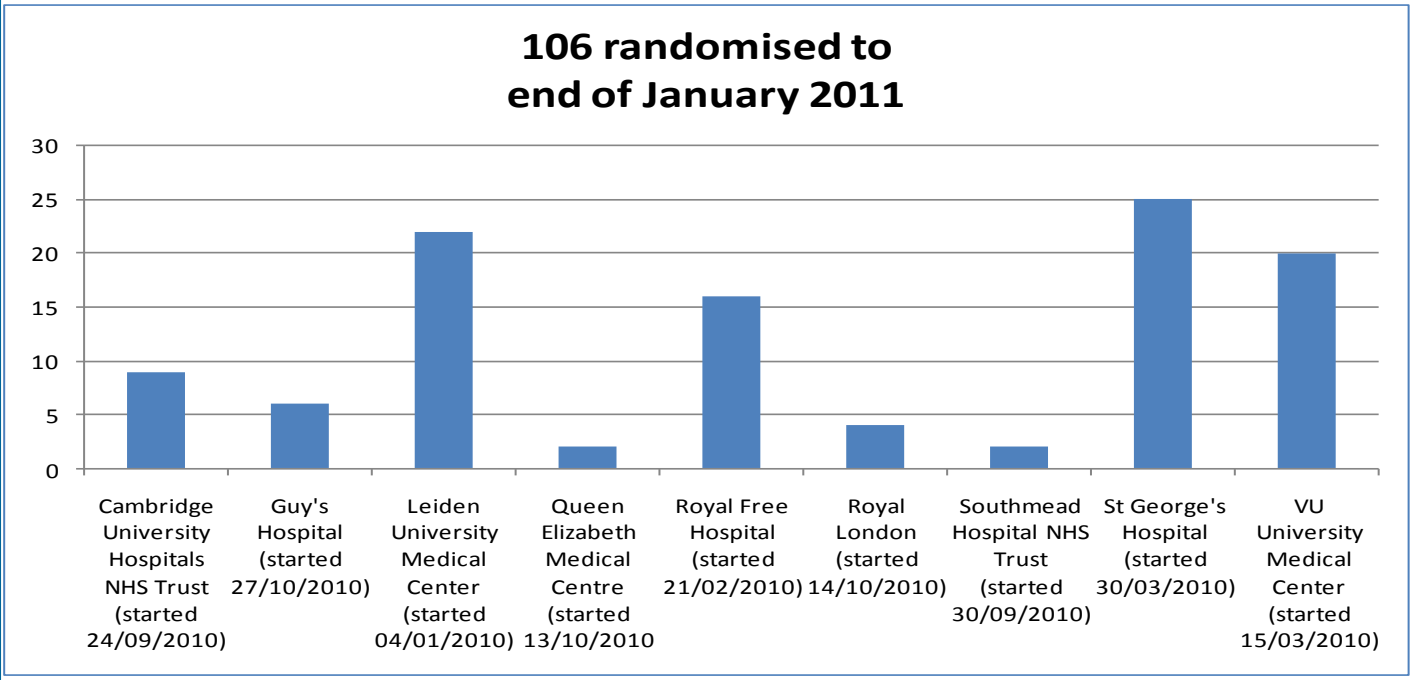
REPAIR Trial Newsletter

REPAIR Renal Protection Against Ischaemia Reperfusion in Transplantation

Issue 11, February 2011

Recruitment update



Protocol changes

Two changes have recently been made to the protocol and have ethics approval.

Immunosuppression regimens — these have been changed to allow centres to give immunosuppression according to their own local practice which reflects the differences within the trial centres.

0,0,0 – mismatched renal grafts - this exclusion criterion has been removed. These patients were originally excluded because their immunosuppression protocol was different from other transplants. However, the changes to the immunosuppression protocol since the original description now enables the recruitment of this small number of patients.

The current protocol is Version 9 dated 13/12/2010. If you do not have this version please visit the website or contact the data coordinating centre.

Feedback from DMC

On the 14th January the REPAIR Data Monitoring Committee (DMC) met to review the data collected so far. The feedback from the DMC was very positive and they passed on their congratulations to the sites for the high quality of data. They are obviously concerned about recruitment and will be keeping a close eye on this over the next few months.

There was only one other slight concern that was discussed and this was the amount of creatinine samples missing immediately post transplant (recovery), 4 and 8 hours post transplant. It was explained that we had suggested to the sites that some of these samples could be missed if they fell out of hours or when it was not performed as routine practice. This was done to increase recruitment as patients were being missed due to no available staff. However if you are able to collect these samples please could you try and do so. On a more positive note the samples collected at 24 hours and 48 hours was nearly 100%.

F.A.Q. — Amiodarone

Question: Should patients on amiodarone be excluded from the trial?

Answer: Amiodarone is a well recognised potassium channel blocker but it does not block ATP sensitive potassium channels so isn't an exclusion criterion. Patients on amiodarone can be included in REPAIR.

REPAIR

Renal Protection Against Ischaemia Reperfusion in Transplantation

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

Paired exchanges

It is possible that the patients in a paired exchange may come from different centres. These pairs can be included in REPAIR as long as the following guidelines are followed.

- The pairs must both be associated with a REPAIR centre, or a Patient Identification Centre (PIC)
- It is likely that the donor for each pair will be randomised locally as they will be in hospital before the recipient. Randomising staff should liaise between the centres prior to randomisation to establish whether donor or recipient will be randomised
- The people randomising will liaise between the centres to ensure the correct interventions are given to each of the patients according to randomised pair rather than location pair
- All data (intervention and follow-up) will be entered centrally at the data coordinating centre. Blinded staff should use the paper CRF to record the data and when completed fax to **020 7637 2853**
- All samples will be labelled with the ID number that was allocated at randomisation to make identification easier when it comes to analysing the samples
- When randomising such pairs always inform the data coordinating centre in advance of the randomisation

If you have any questions regarding a paired exchanged from different centres contact the data coordinating centre by emailing **repair@lshtm.ac.uk**

Contact details

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