REPAIR Trial Newsletter

REPAIR
Renal Protection Against Ischaemia Reperfusion in Transplantation

Issue 6, September 2010

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Eligibility

Inclusion criteria

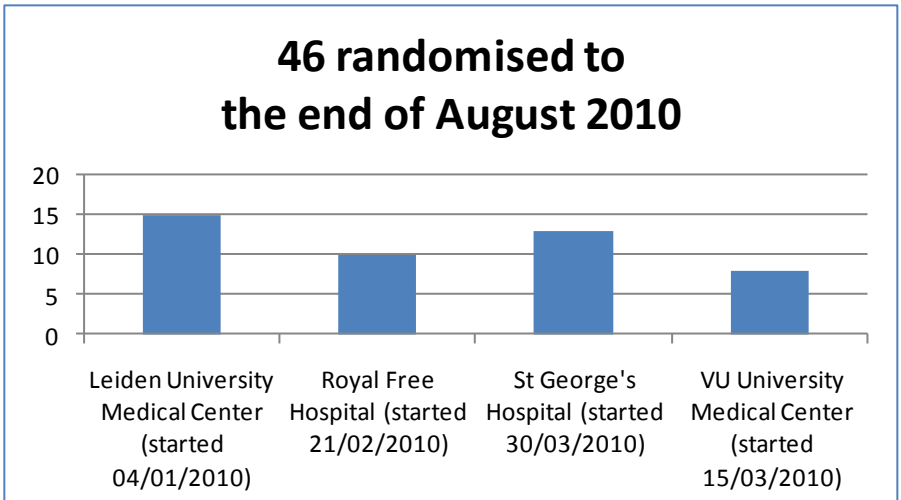
- Patients undergoing living donor transplantation
- Patients aged 18 years and above

Exclusion criteria

- 0,0,0-mismatched renal grafts (no mismatch in HLA-A/B/DR antigens between donor and recipient)
- Patients on ATP-sensitive potassium channel opening or blocking drugs
- Patients on ciclosporin
- Patients who have had a previous transplant
- 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

Recruitment update



July (9) and August (8) have been the best months for recruitment so far, so well done to everyone involved. At least 3 more centres should start recruiting from September so we are confident recruitment rates will continue rising each month. Training went well recently at Guy's, Southmead and QE Birmingham and special thanks to Bristol for providing the best cakes!

Informed consent

Quite a few queries have been asked recently about informed consent and who is responsible for taking it. It is a decision that should be made by the Principal Investigator of the REPAIR trial. The hospital R&D department may also have guidelines on who is covered to take informed consent for the trial. Most hospitals ask for personnel to have undergone GCP training.

It is important that written informed consent is taken before any study procedures are carried out on either the donor or recipient. The consent forms must be signed and dated by both the patient and the person taking the consent. There should be 3 copies of the consent, one for the patient, one for the hospital notes and one copy for the trial coordination centre. The date on the consent form should be the date that is used on the electronic randomisation form.

For further information please refer to the Consent Standard Operating Procedure (SOP) in your site file. If you would like a copy of this document please email us at **repair@lshtm.ac.uk** and we will send you one.

The local PI's perspective—Mark Harber, Royal Free Hospital

REPAIR is very easy to do especially as it is not a drug intervention. Consent has been extremely easy as the intervention is simple, non-invasive and pretty much without any discomfort. Moreover the concept that this study is testing whether a simple intervention (that could be applicable in the developing world) may reduce damage to a live donor kidney is very appealing to both donor and recipient.

From the researcher's perspective it is essentially consent, randomisation, intervention and a few additional bloods plus the 12 month GFR, which most patients see as a bonus in terms of getting a really accurate measure of their kidney function, and which is not routinely available to other patients. Some units are signed up to additional biopsies and research bloods but for the majority it is the standard package.

Occasionally donors have not been able to travel to the unit 24 hours pretransplant for the first intervention and thus have been excluded, but in general there has been a really generous attitude to the study (perhaps not surprisingly from live donors) and most patients are happy to come early in the morning and then spend the rest of the day shopping! None of ours have yet claimed taxi/transport back but this is available and offered as part of the funding for the study.

There is refreshing and laudable national enthusiasm for the 3C study in renal transplantation and we at the Royal Free have also agreed to recruit to this study not least because it probably marks an important step forward in national cooperation with investigator led studies. As the 3C study is recruiting the vast majority of both deceased donor and live donor transplants we will give priority to the REPAIR study to the eligible live donor transplants and offer recruitment to the 3C study to all other patients.

In my experience, having been involved in several trials, the REPAIR study is probably one of the easiest to recruit to and perform.

Participating centres

Centre	**Status (end of August)**
Leiden University Medical Center	Recruiting (15)
St George's Hospital, London	Recruiting (13)
Royal Free Hospital, London	Recruiting (10)
Guy's Hospital, London	Screening patients
Southmead Hospital, Bristol	Screening patients
Leicester General Hospital	Recruiting
Queen Elizabeth Medical Centre, Birmingham	Screening patients, start 1st September 2010
Royal London Hospital	Approval received
Cambridge University Hospitals NHS Trust	Recruiting
VU University Medical Center, Amsterdam	Recruiting (8)

Contact details

If you would like paper copies of the REPAIR newsletter (for wards or outpatient clinics) please email us and we will be happy to provide these.

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