

REPAIR Trial Newsletter



Renal Protection
Against Ischaemia
Reperfusion in
Transplantation

Issue 5, August 2010

Inside this issue

Recruitment update	1
Inclusion/exclusion criteria	1
Investigators' meeting	1
Donor expenses	1
F.A.Q.— donors from abroad	2
Data Monitoring Committee	2
Participating centres	2
Contact details	2

Eligibility

Inclusion criteria

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

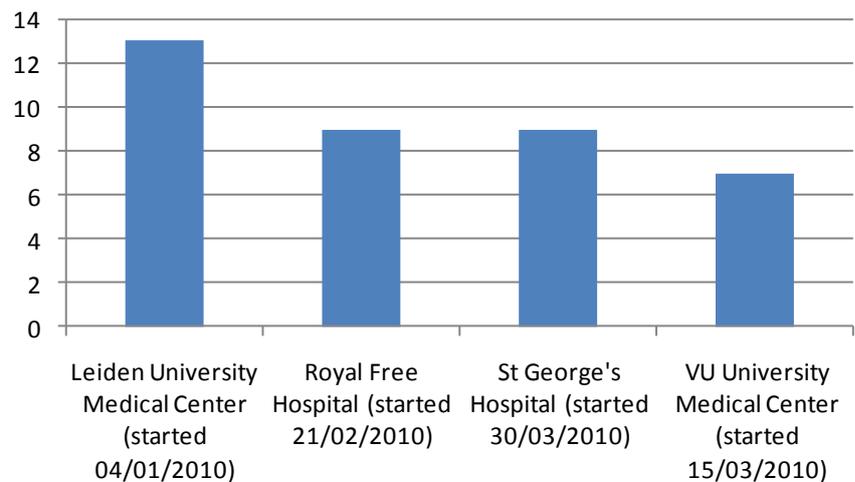
Exclusion criteria

- 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

Number randomised to end of July 2010



38 patients randomised to end of July

Investigators' meeting

The REPAIR investigators' meeting will be held at the London School of Hygiene & Tropical Medicine (LSHTM) on Thursday 9th December from 1.30pm to 5pm. We will cover reasonable travel costs for 3 people from each site who are actively involved in the REPAIR trial. Further details will follow after the summer break. If you have not responded to the invitation please email josenir.astarci@lshtm.ac.uk to confirm whether you would like to attend.

Donor expenses

Following visits to some of the hospital sites there appears to be an issue with the donor being admitted 24 hours pre nephrectomy in order for the allocated procedure to be carried out. We are keen to recruit as many patients as possible and if it would help REPAIR may be able to cover the costs of an overnight stay near your site. If this situation arises please call Rosemary Knight on 020 7927 2473 to discuss further.

FAQ—What if the donor lives abroad?

Question: Can I still recruit a pair if the donor lives abroad and will be returning home after their operation?

Answer: As there is no follow-up data required from the donor it should be possible to include these patients as long as the donor is available 24 hours before the operation to undergo the intervention and to provide any samples pre and post-op up to the point of discharge. If in doubt please call the data coordinating centre on 020 7927 2473 to discuss.

REPAIR

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Contact details

Tel: 020 7927 2473

Fax: 020 7637 2853

Email: repair@lshtm.ac.uk

Web: <http://repair.lshtm.ac.uk/>

Data Monitoring Committee

The Data Monitoring Committee (DMC) is an independent group that monitors the data from the REPAIR Trial to ensure that it is proceeding as planned and that there are no issues surrounding patient safety. The DMC meets every six months in a special two part meeting. In the first part, the trial manager updates the DMC on recruitment, centre involvement and any changes to the protocol. This is followed by a separate "closed" session which involves the DMC members and trial statistician who prepares the data for review. They discuss the interim results and patient safety. If any issues arise the DMC will raise them with the sponsors and prepare recommendations, including in very extreme cases, stopping the trial.



Cono Ariti, LSHTM

The Repair DMC is chaired by Dr Rajesh Kharbanda, Clinical Cardiologist, from The John Radcliffe Hospital in Oxford. His fellow DMC members are Professor Alan Jardine, Professor of Renal Medicine, University of Glasgow and Professor Joan Morris, Professor of Statistics, Queen Mary University of London. The DMC are supported by statistician Cono Ariti from LSHTM who prepares the reports for the closed session. The DMC met in July and wish to thank everyone who provided data and screening log information for the meeting. They plan to meet again in January 2011.

Participating centres

Centre	Status (end of July)
Leiden University Medical Center	Recruiting (13)
St George's Hospital, London	Recruiting (9)
Royal Free Hospital, London	Recruiting (9)
Guy's Hospital, London	Recruiting
Southmead Hospital, Bristol	Approval received
Leicester General Hospital	Recruiting
Queen Elizabeth Medical Centre, Birmingham	Approved and trained, start 1 st September 2010
Royal London Hospital	Approval received
Cambridge University Hospitals NHS Trust	Recruiting
VU University Medical Center, Amsterdam	Recruiting (7)