

REPAIR Trial Newsletter



Renal Protection
Against Ischaemia
Reperfusion in
Transplantation

Issue 4, July 2010

Inside this issue

Recruitment update	1
Changes to the protocol	1
Inclusion/exclusion criteria	1
Collaborators' meeting	1
Participating centres	2
F.A.Q.— donor GFR	2
HLA mismatch data	2
GCP training	2
Website	2
Contact details	2

Eligibility

Inclusion criteria

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

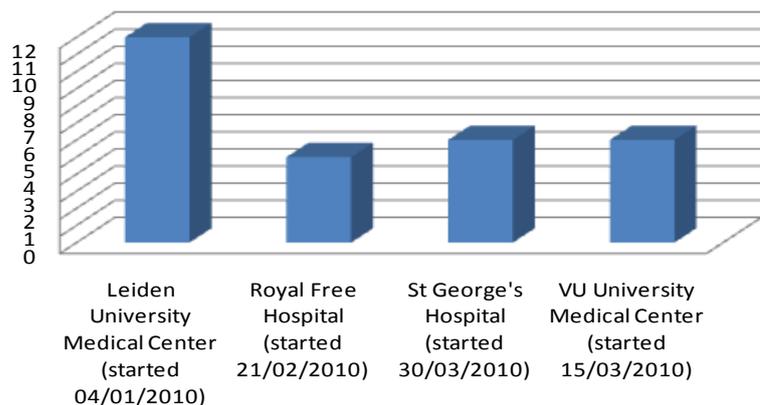
Exclusion criteria

- 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 June 2010



29 patients randomised to end of June

Changes to the protocol

Version 7 of the protocol has just been approved and is available on the website. There were a few amendments but the main changes are as follows:

Page 22: 8.1.3 Mycophenolate/Azathioprine. All patients will receive Mycophenolate or Azathioprine. Mycophenolate will be administered as Mofetil (CellCept) starting at a dose of at least 1gm/day, or Mycophenolate Sodium (Myfortic) starting at a dose of at least 720mg/day. Azathioprine will be administered at a starting dose of Azathioprine 2mg/kg. This has been changed to incorporate Azathioprine usage in some of the hospitals partaking in REPAIR. This was included following feedback from the Principal Investigators.

Page 22: 8.1.4 changed to: All patients will receive Tacrolimus (first dose pre-operatively). Target concentration will be according to local practice. The justification is that target concentrations of Tacrolimus have been adjusted downwards as a result of recent clinical trial data and that this change gives centres greater flexibility to manage the Tacrolimus dose.

FAQ—GFR data for the donor

Question: How do we calculate the donor GFR?

Answer: Originally we asked for the GFR separately for the left and right kidney. However, following a review of the data collection process it became apparent that this is not routinely done in all of the participating centres. So following discussion with the PIs it was agreed only to collect GFR. Additionally we will now also collect divided function data if this is known. The CRF and e-CRF have both been updated to include this change.

HLA mismatch

There has been a small change to the way we are collecting HLA mismatch data. Instead of recording whether there were any mismatches we are now collecting the number of mismatches e.g. 1-1-0. The e-CRF has been revised to allow the numbers to be entered.

Collaborators' meeting

Dates for a meeting in early December have been emailed to you. If you have not already replied please do so to Josemir.Astarci@lshtm.ac.uk as soon as you can.

GCP training

The NIHR offer free Good Clinical Practice training courses for Portfolio registered trials. For further information see <http://www.crncc.nihr.ac.uk/index/training.html>.

Participating centres

Centre	Status (end of June)
Leiden University Medical Center, The Netherlands	Recruiting (12)
St George's Hospital, London	Recruiting (6)
Royal Free Hospital NHS Trust, London	Recruiting (5)
Guys Hospital NHS Trust, London	Approval in progress
Southmead Hospital NHS Trust, Bristol	Approval in progress
Queen Elizabeth Medical Centre, Birmingham	Training confirmed for 8th July
Royal London Hospital, London	Approval received
Cambridge University Hospitals NHS Trust, Cambridge	Recruiting
VU University Medical Center, Amsterdam, The Netherlands	Recruiting (6)
Leicester General Hospital, Leicester	Recruiting



REPAIR

Renal Protection
Against Ischaemia
Reperfusion in
Transplantation

Website

A website has now been launched which will be updated regularly with FAQs and recruitment. The address is

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

Contact details

Tel: 020 7927 2473

Fax: 020 7637 2853

Email: repair@lshtm.ac.uk