

REPAIR Trial Newsletter



Renal Protection
Against Ischaemia
Reperfusion in
Transplantation

Issue 3, June 2010

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Eligibility

Inclusion criteria

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

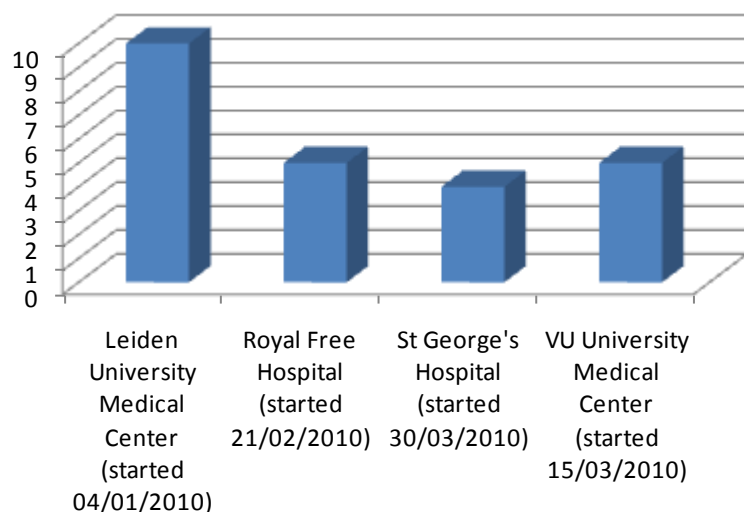
Exclusion criteria

- 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

Number randomised to end of May 2010



24 patients randomised to end of May

Electronic data entry

The web based electronic data entry system has now gone live and centres are able to enter data online. When centres have recruited their first patient we will visit to train the blinded staff to use the system. Training has already taken place at St George's and Royal Free, and was scheduled to take place at Leiden and VU in April but unfortunately the volcanic ash cloud halted our plans! Both sites have however started using the system and additional training will be given during the site monitoring visit. We welcome your feedback on the system and hope it makes the data collection process easier. If you have any comments or queries about this contact Steven Robertson (data manager) by email at steven.robertson@lshtm.ac.uk.

FAQ—blood samples at the weekend

Question: Some REPAIR patients may require cytokine samples to be taken over the weekend. What should happen in these circumstances as there may not be staff available to carry this out?

Answer: The most important issue here is that this should not prevent patients being recruited. Cytokines analysis is a secondary end-point. Therefore it is more important to recruit patients for the study and accept that there might be missing cytokine samples. However, there has to be a pre-operative and at least a single post-operative sample in order to understand the cytokine analysis. The timings of the samples will need to be recorded as usual. In addition it is important that we collect as many of these samples as possible in order that there is sufficient data for the analysis at the end of the study.



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

Site monitoring visits

Several centres have now recruited 5 or more patients and in accordance with our Standard Operating Procedures (SOPs) are due to be visited for monitoring purposes. Visits to Royal Free, Leiden and VU will hopefully take place in June. The purpose is to ensure that trial procedures are being adhered to and that the rights and well being of the participants are being protected within these guidelines. Consent forms and source data will also be verified. Site visits are also an opportunity to discuss and review procedures and try to overcome any obstacles that may be affecting recruitment.

Participating centres

Centre	Current status (end of May)
Leiden University Medical Center, The Netherlands	Recruiting (10)
St George's Hospital, London	Recruiting (4)
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	Approval received, awaiting training dates
Royal London Hospital, London	Approval in progress
Cambridge University Hospitals NHS Trust, Cambridge	Recruiting
VU University Medical Center, Amsterdam, The Netherlands	Recruiting (5)
Leicester General Hospital, Leicester	Recruiting