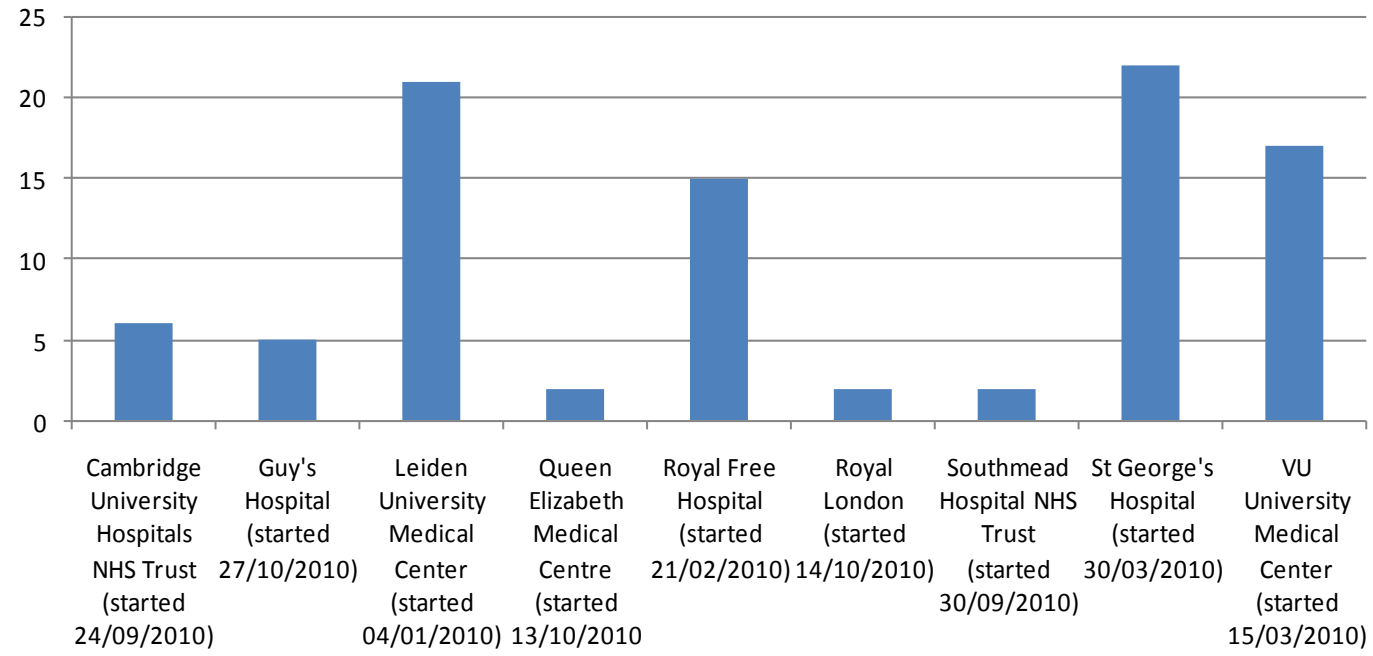
REPAIR Trial Newsletter

REPAIR
Renal Protection Against Ischaemia Reperfusion in Transplantation

Issue 10, January 2011

Recruitment update



1 year on from the start of recruitment

Recruitment to REPAIR started in January 2010 and 1 year on **92** patients have been recruited up to the end of December, and all 9 centres are now actively recruiting. There were some initial problems with obtaining approvals for some centres which held up recruitment in the first half of 2010 which have now been resolved.

The centres who started early in 2010 are recruiting well and two centres have entered more than 20 pairs, and the hospitals who started later on are now starting to pick up which is great news. Four centres have had their first monitoring visit and more visits will follow in 2011.

The first 1 year follow-ups are due throughout January and February. Please try to arrange these within 2 weeks either side of the 1 year post transplant date. This is particularly important with regards to the iohexol clearance. If you would like more information about the iohexol clearance process or require training please let us know.

The investigators' meeting was held in London in December and a review of the day is on page 2.

Report from the investigators' meeting

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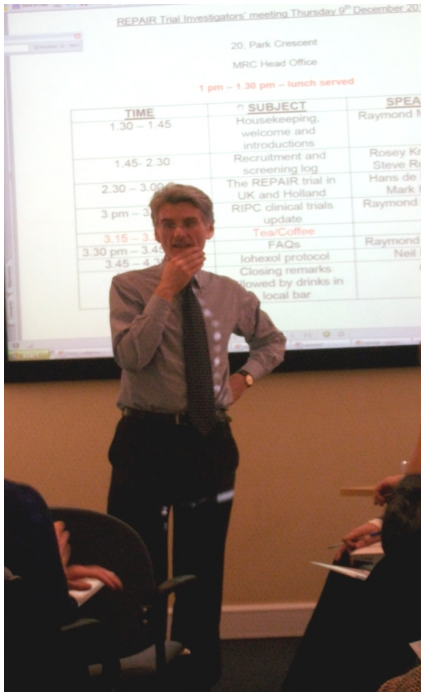
Many thanks to all of you for attending the investigators' meeting on 9th December. It was great to see so many of you. If you haven't already please ensure that you send back your travel claims as soon as possible.

The afternoon went well with many helpful discussions and feedback, particularly in relation to the results of the screening log.

Rosey's talk gave further information on recruitment rates and what we need to achieve to complete the trial by the end of next year, however the milestones for recruitment do need reviewing to give us a realistic time scale for recruitment.

Raymond gave a brief overview of recent trials on RIPC and said most (but not all) trials of RIPC show a positive effect. REPAIR remains an important trial to help answer the question with regard to pre-conditioning.



Raymond MacAllister

Hans de Fitjer and the Leiden experience

Raymond also presented some common FAQs and hopefully helped to clarify issues raised including bloods and centrifuging. The website section has been updated and more information can now be found at http://repair.lshtm.ac.uk/FAQ.htm

Many thanks to both Hans and Mark for presenting their perspective on how the REPAIR trial is organised in both London and Leiden.

Neil gave an excellent presentation on the background to Iohexol testing and also the procedure itself. One of the main issues raised during this was to highlight the fact to the recipient that this test will take around 4 hours to complete. However, the information they provide to us is invaluable as it is the primary endpoint of the study and without this all of the hard work will be in vain. It is also an opportunity for them to have an extensive study of their kidney which they would not normally have outside of the trial. Patients should be reminded about their 1 year follow-up either by a phone call or letter.

If you would like a copy of either Hans's or Neil's talk then please contact the REPAIR office on repair@lshtm.ac.uk.

Centre profile—VU Amsterdam

REPAIR
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The REPAIR trial is carried out by a team of two nurse practitioners and two research nurses. Our transplant centre is relatively young, but dynamic. We do about 26 living kidney transplantations a year.

The nurse practitioners already have close contact with the donors and the recipients because of the pre transplant clinics.

Approximately three to four weeks before the transplantations occur, donors and recipients are informed of the REPAIR trial during a general visit to the clinic.

We take a lot of time to explain the procedure and to answer all their questions. The clear explanations that are given and the enthusiasm of the nurse practitioners means that the patients are more motivated to participate in the research trial. The patients and donors take home the information and the brochure of the medical investigation rules to read at their leisure. We see them again one week before the transplantation. During this visit we ask them if everything is clear and if they are willing to sign the informed consent.

Since we started in March 2010 we have included 17 couples in the trial. Only one patient has refused, although the donor was willing to participate. One couple was not included due to logistical reasons.

The two nurse practitioners are responsible for the interventions. Normally one takes the donor and the other the recipient. The nurse practitioners take it in turns to do the very early intervention of the donors on the day of transplantation.

Patients have said that they do not experience the intervention as stressful or painful. Hospital appointments are also not more than that of our usual transplant participants.

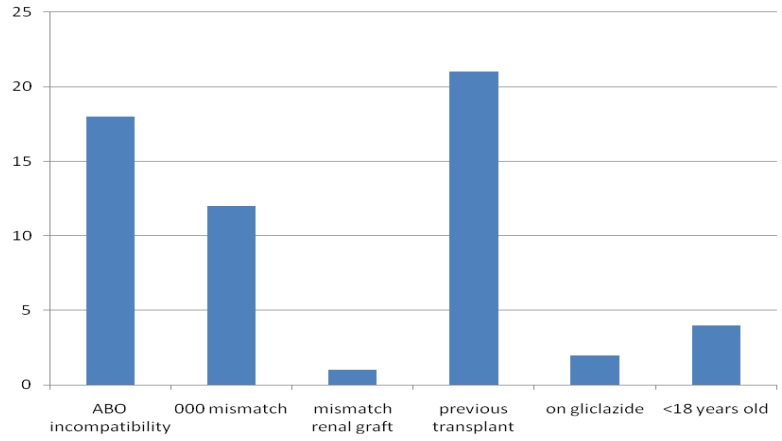
There are clear arrangements made with the nursing staff that the blood samples shall be collected by the research nurses. The blood is taken in conjunction with the regular blood tests so that the patient is not further inconvenienced. If the research nurses are not present, for example in the weekend, the blood is taken by the nephrologists.

The conclusion that we have reached is the success of the REPAIR trial here in the VU hospital in Amsterdam is due to the high motivation and good cooperation of the team.

Carla Schrauwers and Marjon van Vliet, VU Medical Center

Screening log data

Screening log data throughout the year has provided valuable information about patients that are being transplanted but not entered into REPAIR. Data collected up to the end of October 2010 showed that 58/196 patients screened were not entered because they were not eligible according to current criteria. When we looked at the data 33 of the 58 were not eligible due to either having had a previous transplant or being a 000 mismatch.



This has allowed us to review our procedures which will hopefully lead to an increased monthly recruitment rate.

Protocol changes already made: we have removed previous transplant from the list of exclusions and this has been approved by ethics.

Protocol changes pending: remove 000 mismatch from the list of exclusions. This was sent as an amendment to ethics on 14 December 2010. We will notify centres as soon as approval is given.

REPAIR

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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 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

Participating centres

Centre	Status (end of December)
Leiden University Medical Center	Recruiting (21)
St George's Hospital, London	Recruiting (22)
Royal Free Hospital, London	Recruiting (15)
Guy's Hospital, London	Recruiting (5)
Southmead Hospital, Bristol	Recruiting (2)
Queen Elizabeth Medical Centre, Birmingham	Recruiting (2)
Royal London Hospital	Recruiting (2)
Cambridge University Hospitals NHS Trust	Recruiting (6)
VU University Medical Center, Amsterdam	Recruiting (17)

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