

REPAIR Trial Newsletter

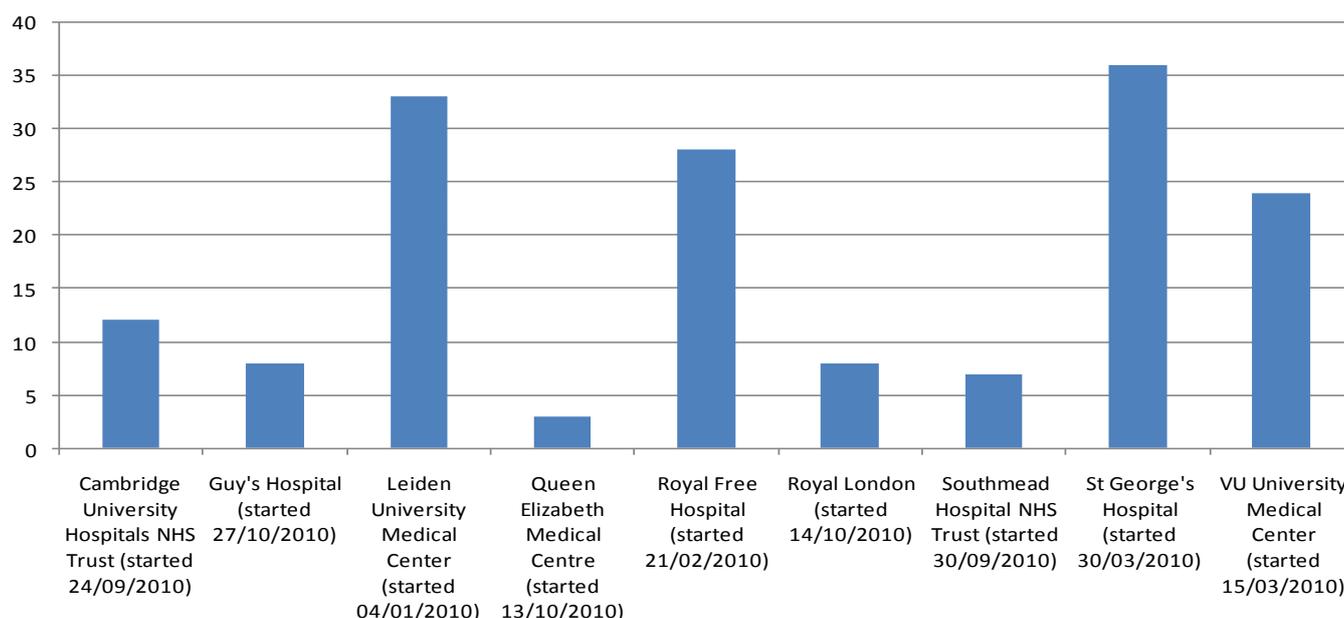


Renal Protection
Against Ischaemia
Reperfusion in
Transplantation

Issue 15, June 2011

Recruitment update

**159 randomised to
31 May 2011**



Intention to treat

REPAIR will be analysed on an Intention to Treat (ITT) basis. Recently a couple of questions have been asked about what this means in practice so we thought it would be helpful to add something to the newsletter. For those who would like further information there is more included in the book 'Clinical Trials: A Practical Guide to Design, Analysis and Reporting' by Duolao Wang and Ameet Bakhai.

An ITT analysis means that patients are analysed in the groups to which they were randomised irrespective of whether the allocated treatment was carried out or not, or was incomplete. So if a patient only has part of the allocated treatment or if the intervention was not carried out, they will still be included on the basis that the randomised allocation was carried out. This method of analysis is used widely in many trials and offers a more pragmatic approach. This approach is less likely to lead to bias and more closely reflects the impact of treatment as it would apply in clinical practice by recognising that not all patients will comply with treatment policy.

It is also important that even if the patients do not complete the allocated intervention they should still remain within the trial and be followed up as normal. The only reason patients should not be followed up is if they specifically request to be withdrawn from the trial but it is expected that this would apply to very few patients, if any. If in any doubt then please contact the REPAIR office for further advice if required.

Timing of intervention for both donor and recipient

The first wave of preconditioning is activated immediately the intervention is applied and lasts for around 4 hours. For this reason it is important that the intervention on the day of transplantation is applied as close as possible to the time of surgery, as typically the operation lasts in the order of 4 hours.

The first intervention should be carried out 24 hours before surgery (plus or minus 2 hours). This allows the second wave of preconditioning, which is activated at around 24 hours after the intervention, to also take effect by the time of the operation.

Despite our best efforts, this may be difficult to ensure in all cases. If the intervention occurs outside the time limits specified above, the patients should still be included in the study. If it is known in advance that there will be a timing issue with a particular pair, again they should not be excluded from the study for this reason. The time of the intervention is documented, and we now ask that the time of induction of anaesthetic (donor and recipient), the clamp time (donor) and reperfusion time (recipient) are recorded. This will enable us to analyse these results.

Large blood pressure cuffs

These are now available from the REPAIR office. Any centre requiring one should contact Josemir.Astarci@lshtm.ac.uk at the REPAIR office.



Eligibility

Inclusion criteria

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

Exclusion criteria

- 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

Update from the Data Monitoring Committee (DMC)

The DMC reviewed the data again on the 6th May. The chair reported back that they were again impressed with the quality of the data collected. Whilst the main review of the data remains closed to all apart from Cono Ariti (trial statistician) and the DMC members, no issues have been raised. The DMC will meet again on the 25th November 2011, when there will be more 1 year data to review.

St George's change of PI

We would like to say a big thank you to Jiri Froněk who has been the PI at St George's for the last 2 years and has led an excellent team that has so far recruited over 30 pairs. Jiri is leaving to return to Prague and we wish him every success over there. Taking over as PI is Nicos Kessaridis and we would like to welcome him and look forward to working with him on the study.

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