

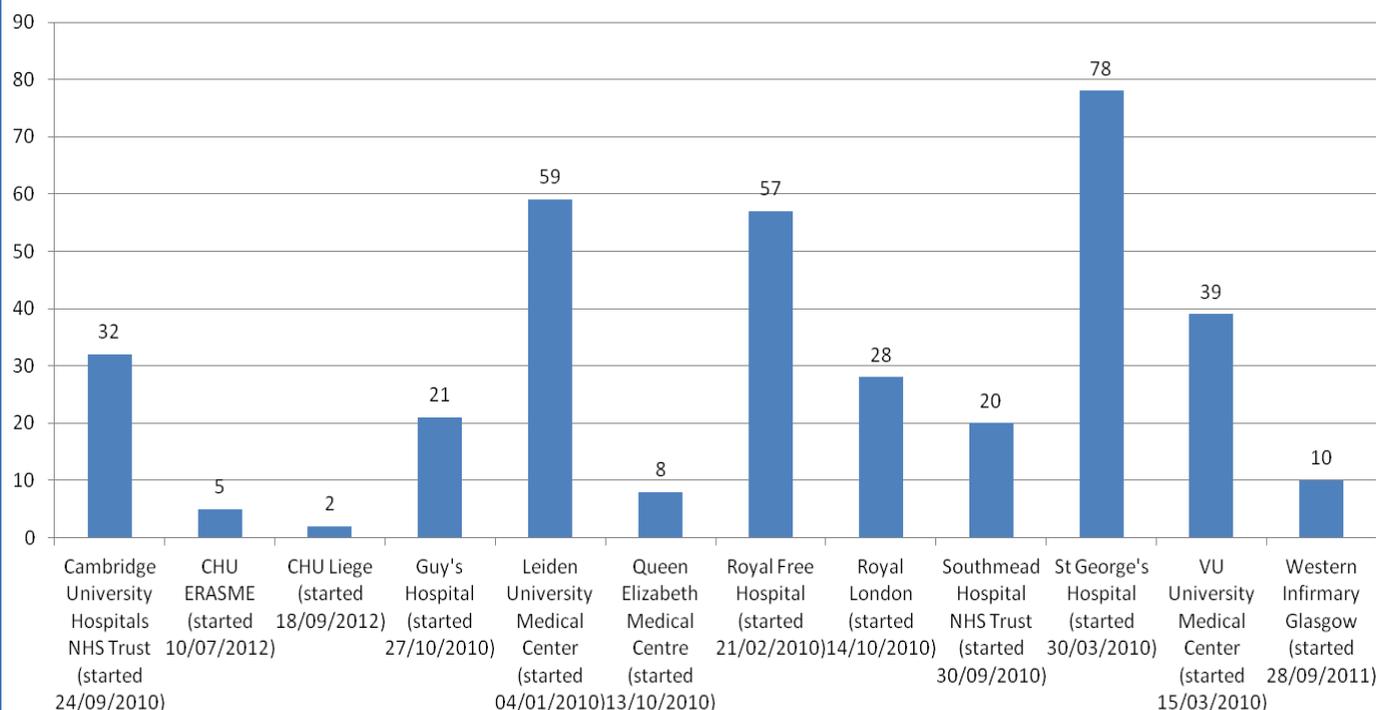
# REPAIR Trial Newsletter



Issue 33 December 2012

## Recruitment update

359 randomised to  
end of November 2012



November has been the best month ever for recruitment with 19 pairs randomised! The previous best was 18 in October 2011 so well done everyone! The last few months have been excellent for recruitment and we hope this momentum will continue until the end of recruitment on 30th April 2013. December is usually a quieter month due to holidays so please include all eligible pairs that are transplanted throughout the month.

## Want to know more about clinical trials?

Clinicians, policy makers and patients are increasingly demanding high quality evidence to help with making decisions about health care. Randomised Controlled Trials (RCTs) provide much of the evidence needed to register new drugs for use, but trials are also used for comparing a wide range of non-drug treatments, such as medical versus surgical managements for cancer.

LSHTM runs an annual short course in clinical trials which provides an introduction to the area of clinical trials, particularly phase III trials, with more detailed coverage of some of the key issues to be considered in their design, analysis and interpretation.

The next course runs from 10-14 June 2013. If you are interested in this course please visit <http://www.lshtm.ac.uk/study/cpd/sct.html> in the first instance.

## Frequently Asked Questions

**Question:** Are patients who are receiving intravenous immunoglobulin (IVIG) excluded from REPAIR?

**Answer:** Yes, these patients should be excluded from REPAIR. Therapies such as plasma exchange and IVIG are sometimes used before transplantation for patients who are either blood group incompatible, or have high levels of donor specific antibodies in their blood. These therapies remove antibodies from the blood, and so will alter the immune response during and following kidney transplantation. Such treatments may therefore improve kidney function, in a way that is not related to preconditioning. This could potentially confuse the results of the study.

## Feedback from DMC and TSC

The Data Monitoring Committee (DMC) met on 16<sup>th</sup> November to review the data. They would like to thank all centres for submitting data and samples in time for the review. The next meeting is on 14<sup>th</sup> June 2013.

The Trial Steering Committee (TSC) met on 12<sup>th</sup> November. Following the meeting the chair, Tom Meade, wrote to all centres confirming the recruitment period has been extended until 30<sup>th</sup> April 2013 to try to achieve the full sample size of 400 which will maximise the reliability of the results. He said recruitment has been excellent over the last few months and hopes that centres will continue to support the trial by recruiting during these extra few months. He also mentioned that 2 sites in Belgium who have recently started recruiting and 2 more who are due to start recruiting soon will benefit from this extended recruitment period. The committee are due to meet again in November 2013 and this meeting will include discussions on publication plans with the aim of reviewing the results in April 2014.

## Office closures

The REPAIR trial office will close at 5pm on Friday 21st December and re-open at 08:30 on Thursday 3rd January 2013. During this time there will be limited cover. If you have any urgent medical queries please contact Raymond Macallister ([r.macallister@ucl.ac.uk](mailto:r.macallister@ucl.ac.uk)) from 29 December until 1st January and Kristin Veighey ([kristin.veighey@nhs.net](mailto:kristin.veighey@nhs.net)) at other times. Please also refer to the FAQ section on the website. In addition to this Steve will be on annual leave from 21st December returning on Monday 21st January. During this period all queries should be sent to [repair@lshtm.ac.uk](mailto:repair@lshtm.ac.uk).

There will be no newsletter at the start of January but a recruitment update will be sent out the week beginning 17th December.

## 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

## Contact details

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