

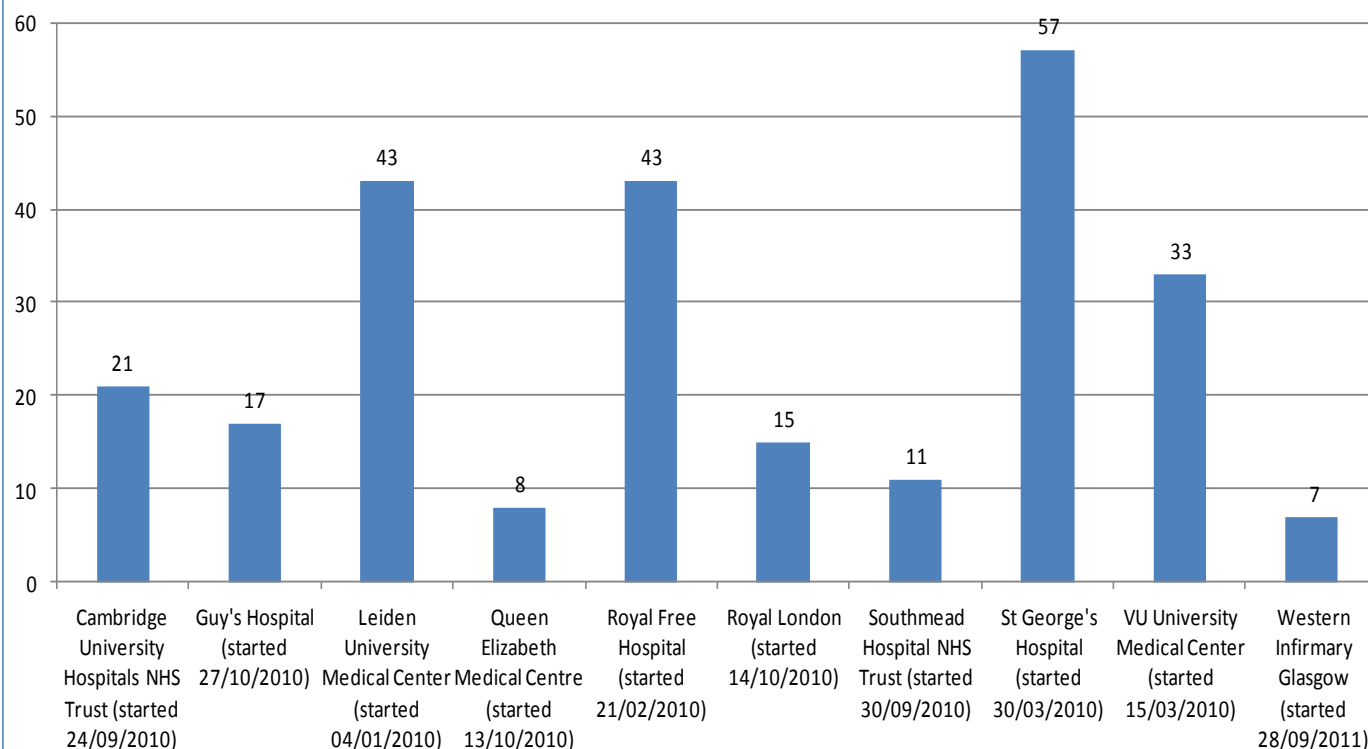
REPAIR Trial Newsletter



Issue 24, March 2012

Recruitment update

255 randomised to
29 February 2012



Feedback from the Data Monitoring Committee

The REPAIR Data Monitoring Committee (DMC) met on 27th January 2012. This was the first opportunity for Jenny to review the data in her role as DMC statistician. Although no specific recommendations were made the committee would like to thank everyone involved for their continued support of the trial and encouraged all centres to continue entering all eligible patients to maximise recruitment. They emphasised the importance of completing the iohexol clearance test at 1 year (which as you are all aware is the end point) as without these the final results are likely to be diluted. A teleconference will be arranged for 4th May 2012 for the DMC to specifically look at the results of the first few batches of iohexol samples that have been sent to the Royal Free Hospital (RFH) and then sent to Neil Dalton for the analysis. Many thanks to all the sites who have already sent on their samples. If you would like to transfer any other samples then please liaise with Rosey or Kristin (kristin.veighey@nhs.net) to ensure all samples are received in good time to be analysed prior to the teleconference.

We can provide boxes for samples to be stored correctly for transferring which helps when they reach the RFH. Please contact the REPAIR office if you need any supplies or advice with arranging the courier.

Frequently Asked Questions

Question: Some patients have contacted the REPAIR nurse at the hospital asking if they are allowed to have a decaffeinated drink prior or during the Iohexol test. Is this ok?

Answer: This has been checked with Neil Dalton and Kristin and both have confirmed that it is fine for patients to have decaffeinated drinks as they will not interfere with the outcomes of the test.

Site monitoring

Following a recent review by the Quality Assurance Manager at the Clinical Trials Unit at LSHTM we are making some changes to our site monitoring procedures which we hope will help simplify processes both with the sites and the coordinating centre. It was felt that it will no longer be necessary to monitor 1 year data as the primary endpoint is based on the iohexol clearance samples which will be measured in an independent laboratory. However, a further visit may be required at 1 year if:

- A centre requests a visit to discuss specific issues or areas of concern, or wants help or training with trial procedures
- The trial coordinating centre feels a visit is required due to concerns about the way the trial is being conducted at a site.

A revised Standard Operating Procedure (SOP) document is currently being approved by Tom Meade who is chair to the Trial Steering Committee (TSC) and will be circulated shortly. If you have any questions about monitoring please contact steven.robertson@lshtm.ac.uk.

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

Investigator meeting 2012

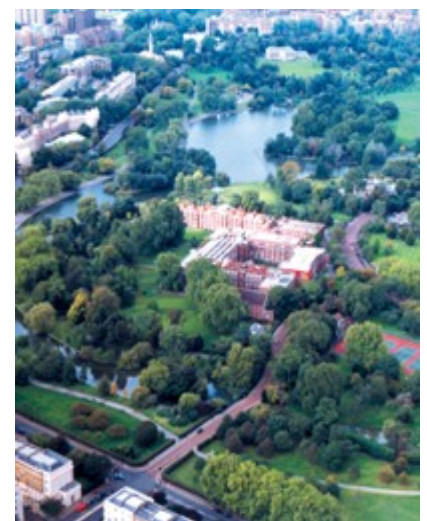
The date is confirmed as Friday 27th April. Apologies to those who are unable to attend on that date.

The meeting starts at 1:00pm, with lunch available from 12:30pm, and finishes at 4:30pm. The afternoon will be followed by drinks.

The venue is Regent's College, Tuke Common Room, Inner Circle, Regent's Park, London NW1 4NS. The nearest tube stations are Baker Street and Regent's Park. For further information please visit www.regentsconferences.co.uk.

We will reimburse reasonable travel expenses (**2nd class train fare/economy air fare**). Please keep your ticket receipts.

The agenda will follow nearer the time and we look forward to seeing you all there.



Regent's College, London

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