

Renal protection against ischaemia-reperfusion in transplantation

Submission date
08/06/2009

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
09/07/2009

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
29/05/2015

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EME 08/52/02; 2 version 7

Study information

Scientific Title
Renal protection against ischaemia-reperfusion in transplantation: a double-blind randomised controlled trial with a factorial design

Acronym

REPAIR

Study objectives

Remote ischaemic preconditioning reduces ischaemia reperfusion injury to the kidney in living-donor transplantation and improves kidney function.

Link to EME project website: <http://www.eme.ac.uk/projectfiles/085202info.pdf>

Link to protocol: <http://www.eme.ac.uk/projectfiles/085202protocol.pdf>

Please note that as of 04/08/10 this record has been updated to reflect changes to the exclusion criteria in the latest protocol (v.7). Please see the relevant section for more details.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University College London Hospitals Local Research Ethics Committee (UCLH LREC) Committee alpha, 08/06/2009, ref: 09/H0715/48

Primary study design

Interventional

Study design

Double-blind factorial design randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Kidney transplantation

Interventions

The trial will test whether a simple procedure, the application of a blood pressure cuff to the arm of the donor and the recipient before a kidney transplant, can help protect the donor kidney from the harmful effects of the transplant. The blood pressure cuff to be used is similar to the one that is used to measure blood pressure. It will be inflated continuously for a five-minute period, after which it will be deflated for 5 minutes. This cycle of inflation, followed by deflation, will be performed 4 times in total.

The trial follow up is 5 years, performed in the context of routine clinical follow up.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Glomerular filtration rate (GFR) 12 months after transplantation.

Key secondary outcome(s)

1. Rate of fall in creatinine in the first 72 hours after transplantation
2. Inflammatory response to surgery in the first 5 days after transplantation

3. Protein expression in kidney parenchyma samples using histochemistry
4. Protein activation and expression in renal vasculature using immunoblotting
5. Kidney fibrosis 6 months after transplantation
6. Alloreactivity of T-cells in the first 18 months after transplantation
7. Patient outcomes 2 - 5 years after transplantation using renal registry data

Completion date

01/04/2013

Eligibility

Key inclusion criteria

1. Patients undergoing living donor transplantation
2. Patients aged 18 years and above, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. 0,0,0-mismatched renal grafts (no mismatch in HLA-A/B/DR antigens between donor and recipient)
2. Patients on adenosine triphosphate (ATP)-sensitive potassium channel opening or blocking drugs
3. Patients on ciclosporin
4. Patients who have had a previous transplant
5. Patients with a known iodine sensitivity (who cannot undergo iohexol clearance studies)

Added 04/08/2010:

6. Patients with ABO incompatibility
7. Any patient requiring HLA antibody removal therapy

Date of first enrolment

01/10/2009

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

United Kingdom

England

Netherlands

Study participating centre

BHF Laboratories

London

United Kingdom

WC1E 6JJ

Sponsor information

Organisation

University College London (UCL) (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme (ref: EME 08/52/02)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------|---------|--------------|------------|----------------|-----------------|
|-------------|---------|--------------|------------|----------------|-----------------|

[Results article](#)

results

01/05/2015

Yes

No