# Renal protection against ischaemia-reperfusion in transplantation

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
08/06/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/07/2009	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
29/05/2015	Injury, Occupational Diseases, Poisoning			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

#### Secondary identifying numbers

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 lastest protocol (v.7). Please see the revelant 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

#### Study design

Double-blind factorial design randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### 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 measure

Glomerular filtration rate (GFR) 12 months after transplantation.

#### Secondary outcome measures

- 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

#### Overall study start date

01/10/2009

#### 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

400

#### 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 incompatability
- 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

England

Netherlands

United Kingdom

# Study participating centre BHF Laboratories

London United Kingdom WC1E 6JJ

# Sponsor information

#### Organisation

University College London (UCL) (UK)

#### Sponsor details

Joint Biomedical Research Unit 1st Floor, Maple House 149 Tottenham Court Road London England United Kingdom W1T 7NF

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r.macallister@ucl.ac.uk

#### Sponsor type

University/education

#### Website

http://www.ucl.ac.uk/joint-rd-unit/about-us

#### **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**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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