ISRCTN30083294 https://doi.org/10.1186/ISRCTN30083294

Renal protection against ischaemia-reperfusion in transplantation

Submission date	Recruitment status
08/06/2009	No longer recruiting
Registration date	**Overall study status**
09/07/2009	Completed
Last Edited	**Condition category**
29/05/2015	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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
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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