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Pre-transplant machine perfusion of heart-beating donor kidneys prior to renal transplantation

Submission date 30/03/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 10/05/2005	**Overall study status** Completed	
Last Edited 10/08/2017	**Condition category** Surgery	

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
2005-001495-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multi-centre, randomised, controlled study of pre-transplant machine perfusion of heart-beating donor kidneys prior to renal transplantation

Acronym
HBDPump 2005

Study objectives
Primary objective:
To determine whether a brief period of machine perfusion reduces the incidence of delayed graft function following renal transplantation.

Secondary objective:
To evaluate the cost effectiveness of a brief period of machine perfusion prior transplantation.

Please note that as of 24/02/2009 this record was updated to include amendments to the trial information. The trial has been changed from single centre to multicentre, and the acronym has been altered from 'CamPump' to the current acronym. At this time, the trial dates on this record were also amended; the overall trial dates at the time of registration were:
Initial overall trial start date: 01/08/2005
Initial overall trial end date: 31/08/2010

Ethics approval required
Old ethics approval format

Ethics approval(s)
The London Research Ethics Committee (REC), 02/02/2006, ref: 05/MRE02/75

Study 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, use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Kidney preservation prior to transplantation

Interventions
Machine perfusion of the kidney before transplantation versus simple cold storage

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Incidence of delayed graft function at 7 days

Secondary outcome measures
1. Patient survival
2. Graft survival
3. Graft function - estimated glomerular filtration rate (GFR)
4. Acute rejection incidence
5. Acute rejection severity
6. Incidence of steroid resistant rejection, defined as the need for ATG therapy

Overall study start date
28/06/2006

Completion date
30/06/2012

Eligibility

Key inclusion criteria
Patients (aged 18 years and over, either gender) undergoing transplantation of a kidney from a heart-beating cadaver donor.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
Added 24/02/2009: Multi-organ recipient

Date of first enrolment
28/06/2006

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's Hospital (UK)

Sponsor details
Hills Road
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Addenbrooke's Hospital (UK) - transplant research fund

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