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Cold Pulsatile Perfusion in Asystolic donor Renal Transplantation

Submission date 31/03/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/05/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 04/02/2016	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Kidneys from deceased organ donors need to be preserved out of the body to allow time for them to be allocated to a recipient, transported to the recipient centre, and for the recipient to be brought in and prepared for surgery. Typically this takes 12 to 18 hours. Traditionally preservation has been achieved by simply flushing the kidneys with a special preservation solution and placing them in a container of ice. An alternative is to put the kidney on a machine to continuously flush preservation fluid through the kidney until it is time to transplant the kidney into a recipient. The aim of this study is to see which method is superior for kidneys donated by deceased organ donors after circulatory death (DCD).

Who can participate?
Patients aged 18 and over undergoing transplantation of a kidney from a deceased organ donor.

What does the study involve?
Donated kidneys are randomly allocated such that one kidney of a pair is placed on the perfusion machine while the other is flushed and stored in ice until transplantation. Both kidneys of a pair are transplanted at the same centre. The transplant recipients are then followed up to see whether the kidney worked immediately or whether there was a delay in it starting normal function – around half of kidneys from DCD donors do not work immediately and the recipient needs to continue on dialysis until it does work.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2006 to February 2009

Who is funding the study?
Novartis Pharmaceuticals and Organ Recovery Systems

Who is the main contact?
Mr Christopher Watson

Contact information

Type(s)
Scientific

Contact name
Mr Christopher Watson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multicentre randomised controlled study of cold Pulsatile Perfusion in Asystolic donor Renal Transplantation

Acronym
PPART

Study objectives
Primary objective:
To evaluate the effect of machine perfusion on the incidence of primary function post renal transplantation.

Secondary objective:
To evaluate the cost effectiveness of machine perfusion in asystolic donor kidney transplantation.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The London Research Ethics Committee (REC), 02/02/2006, ref: 05/MRE02/74). Last ethics progress report dated 05/03/2008: favourable ethical opinion given 19/03/2008.

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, please 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
1. Incidence of delayed graft function (need for dialysis in the first 7 days)
2. Calculated glomerular filtration rate (GFR) (MDRD technique) at 7 days

Secondary outcome measures
1. Patient survival
2. Graft survival
3. Renal function measured using calculated GFR
4. Never function rate
5. Time to last dialysis post transplant
6. Acute rejection incidence
7. Cost comparison at one and five years

Overall study start date

18/08/2006

Completion date
28/02/2009

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
205

Key exclusion criteria
Added 24/02/2009:
1. Lack of informed consent
2. Positive cross-match
3. Previous recipient of non-renal transplant

Date of first enrolment
18/08/2006

Date of final enrolment
28/02/2009

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2010		Yes	No