

CArdiac Death kidney Machine Perfusion trial

Submission date 05/04/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/09/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/11/2018	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol

Background and study aims

There is an international shortage of kidneys for transplantation, and there is great interest in optimising the kidneys available, in order to ensure that kidney transplants last for as long as possible with the best long-term function. When kidneys are recovered from deceased donors they inevitably face a period of storage while they are shipped to the recipient hospital and the logistics of transplantation are put into place. It has been shown that this period of storage can be harmful to kidneys and so this study aims to test which of two commonly used storage techniques is best for kidney transplant outcome. The first technique is 'cold static storage' in which the kidney is placed in cold preservation solution and transported in a box of ice. The second is 'cold pulsatile machine perfusion' in which the kidney is placed on a machine that pumps preservation fluid around the kidney.

Who can participate?

Adult recipients of kidney transplants.

What does the study involve?

Kidneys for transplant will be randomly allocated to either be placed upon the pulsatile perfusion machine or placed in a standard cold-storage ice-box. The kidney transplant recipients will be asked if their information may be followed up.

What are the possible benefits and risks of participating?

Both kidney storage techniques are commonly used in clinical practice outside the study, and we do not anticipate any additional risks from taking part in the study over the standard risks of transplantation but, as many patients will require further transplants, the information gained from this study may help them in future.

Where is the study run from?

The study is being run from Cambridge, with patients from Leeds, Manchester, Edinburgh and Glasgow also taking part.

When is the study starting and how long is it expected to run for?

From April 2011 to May 2017.

Who is funding the study?
NHS Blood and Transplant (UK).

Who is the main contact?
Professor Chris Watson

Contact information

Type(s)
Scientific

Contact name
Prof Chris Watson

Contact details
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Additional identifiers

Protocol serial number
A092044 version 1.1

Study information

Scientific Title
A multicentre randomised controlled study of machine perfusion on cardiac death donor kidneys

Acronym
CAD-MP

Study objectives
Cold pulsatile machine perfusion reduces the incidence of delayed graft function in cardiac-death donor kidneys for transplantation, when compared to simple cold storage.

On 26/06/2015 the overall trial end date was changed from 06/08/2012 to 01/12/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, Cambridgeshire 2 Research Ethics Committee, 08/03/2011, ref: 11/H0308/3

Study design

Multicentre randomised controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Kidney transplantation

Interventions

One kidney will be placed upon the LifePort pulsatile perfusion machine. The other will be placed in standard cold-storage ice-box

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Delayed graft function - the need for dialysis within the first week following transplantation

Key secondary outcome(s)

1. Duration of delayed graft function
2. The area under the curve of the daily serum creatinine level at days 1 to 14
3. Day 14 calculated estimated Glomerular Filtration Rate (eGFR) [abbreviated Modified Diet in Renal Disease (MDRD) technique]
4. The need for dialysis in the first 7 days excluding the first 24 hours post transplant
5. Median times to last dialysis
6. Non-graft function rates, defined as a kidney transplant that fails to provide one month of dialysis free renal replacement, where loss is not attributable directly to rejection or vascular thrombosis
7. Incidence of acute rejection
8. Three and twelve month graft survival
9. Three and twelve month serum creatinine
10. Three and twelve month glomerular filtration rate (MDRD method18)
11. Incidence of graft loss for technical reasons, e.g. renal artery or vein thrombosis
12. One year patient survival
13. Length of hospital stay

Completion date

31/05/2017

Eligibility**Key inclusion criteria**

1. Patients who receive a kidney transplant from a controlled or uncontrolled cardiac-death deceased donor
2. Recipient over the age of 18

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Lack of informed consent
2. Positive crossmatch
3. Previous recipient of non-kidney solid-organ transplant

Date of first enrolment

06/04/2011

Date of final enrolment

01/12/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)**Funder type**

Government

Funder Name

NHS Blood and Transplant (UK) (ref: UKT07/2)

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?
Basic results		23/11/2018	23/11/2018	No	No