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A study of a new technique for organ preservation

Submission date	Recruitment status	[_] Prospectively registered
01/08/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2014	Surgery	

Plain English summary of protocol

Background and study aims
Organs from donors dying following cessation of the circulation suffer excess damage due to being without a supply of oxygen and nutrients for a period before cold storage, a circumstance described as warm ischaemia. Following transplantation this may result in the organs functioning poorly or, occasionally, not at all. We wished to study a new technique to try to overcome this damage, or to enable irreversible damage to be identified before the organs are used.

Who can participate?
Deceased solid organ donors aged 18 to 70 dying on an intensive care unit.

What does the study involve
In order to reverse the initial period of warm ischaemic injury we evaluated a technique of restoring a blood supply to the organs before removal to allow them to recover from ischaemia before cooling them down for package and transport to the recipient. The technique involved using an oxygenator and pump system similar to that used when patients undergo cardiopulmonary bypass surgery, and connecting this to the donor following death. In this way the organs received a supply of oxygenated donor blood at normal body temperature (37°C). Following two hours the organs can then be flushed with cold preservation solution as is the normal practice.

What are the possible benefits and risks of participating?
There are no benefits or risks to the donor, who is dead already. There is a risk that the organs may suffer a complication of the technique, the most likely being a blood clot (thrombosis), but this is prevented by the use of high doses of heparin.

Where is the study run from?
Addenbrookes Hospital (UK).

When is the study starting and how long is it expected to run for?
The study ran from October 2009 to October 2011.

Who is funding the study?
The Evelyn Trust (UK).

Who is the main contact?
Mr Chris Watson

Contact information

Type(s)
Scientific

Contact name
Mr Chris Watson

Contact details
Department of Surgery
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Cambridge
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NRP01

Study information

Scientific Title
A non-randomised controlled pilot study of normothermic regional perfusion in organ donors following cardiac death

Study objectives
Normothermic perfusion will improve the outcome of organs from donors dying following cardiac death and increase the utilisation of organs from each donor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 3 Research Ethics Committee, 21/09/2009, ref: 09/H0306/72

Study design

Non-randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Organ transplantation

Interventions
Control arm: cannulae will be placed in the aorta and vena cava and cold Soltran™ preservation solution perfused through the abdominal organs, following which they will be removed. Duration: 30 to 60 minutes.
Intervention arm: Cannulae will be placed into the aorta and vena cava and blood pumped from the vena cava through a extra-corporeal membrane oxygenator back into the aorta to provide regional perfusion of the abdominal organs. After 120 to 240 minutes they will be flushed perfused with cold Soltran™ preservation solution and removed.

The only follow up is in the organ recipients, who will be followed up for 3 months following transplantation.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Number of potential organs used for transplantation

Secondary outcome measures
Measured at 3 months:
1. Measures of function in the first week post-transplantation
2. Graft and patient survival for liver, kidney and pancreas

Overall study start date
01/10/2009

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Individuals dying on an intensive care unit diagnosed by cardiac criteria and becoming solid organ donors
2. Deceased donors: aged 18 to 70 years, either sex; Recipients: aged 18 to 75 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Time from withdrawal of treatment to death over 2 hours

Date of first enrolment
01/10/2009

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Surgery
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/research/research_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
The Evelyn Trust (UK)

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	27/06/2014		Yes	No