

A study of a new technique for organ preservation

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

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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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Non-randomised controlled single-centre trial

Study type(s)

Other

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(s)

Number of potential organs used for transplantation

Key secondary outcome(s)

Measured at 3 months:

1. Measures of function in the first week post-transplantation
2. Graft and patient survival for liver, kidney and pancreas

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre**Department of Surgery**

Cambridge

United Kingdom

CB2 0QQ

Sponsor information**Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

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

Funder(s)**Funder type**

Charity

Funder Name

The Evelyn Trust (UK)

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?
Results article	results	27/06/2014		Yes	No