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Cold oxygenated machine preservation of aged renal donation after cardiovascular death transplants

Submission date
24/10/2013

Recruitment status
No longer recruiting

Registration date
11/12/2013

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Kidney transplantation is a successful treatment for end-stage renal disease. The standard method of storing and transporting a kidney for transplantation is to perfuse with a cold perfusion solution and store the kidney in an ice box. It has already been shown that machine perfusion preservation improves short term graft function. The aim of this study is to assess whether adding oxygen during the hypothermic machine perfusion (HMP) will reduce damages, decrease ischaemia-reperfusion injury and improve graft function.

Who can participate?
Kidneys donated after circulatory death from donors who are 50 years old or older transplanted into 2 different recipients.

What does the study involve?
Two groups will be compared: a control group (hypothermic machine perfusion with no addition of oxygen) and an intervention group (hypothermic machine perfusion with added oxygen).

What are the possible benefits and risks of participating?
It has been shown that machine perfusion preservation improves short term graft function. The addition of oxygen during hypothermic machine perfusion may be beneficial and may improve graft function.

Where is the study run from?
The trial will be carried out in academic hospitals with an active adult kidney transplant programme in Belgium, the Netherlands and the Southern region of the United Kingdom and their donor hospitals. The lead centre will be University Hospitals Leuven, Belgium.

When is the study starting and how long is it expected to run for?
February 2015 to June 2018

Who is the main contact?
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Additional identifiers

Protocol serial number
s55952

Study information

Scientific Title

A multicentre, double blind, randomised, parallel-group, paired trial to compare the effect of hypothermic machine perfusion preservation with and without the addition of oxygen in transplantation of Maastricht category III kidneys donated after circulatory death from donors aged 50 years or older

Acronym
COPE-COMPARE

Study objectives
Oxygenated hypothermic machine perfusion (HMP) is superior for storage of kidneys of donation after cardiovascular death (DCD) category III donors than non-oxygenated (HMP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commissie Medische Ethiek UZ Leuven, September 2014, ref: ML10722

Primary study design
Interventional

Study design
Randomised controlled surgeon, patient and treating physician blinded multicentre superiority trial with two parallel groups

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Machine perfusion preservation techniques of kidney grafts

Interventions
Hypothermic machine perfusion (HMP) with and without the addition of oxygen.

Group 1 control group: the kidney will be placed on the Kidney Assist HMP device and perfused with Belzers Machine Preservation Solution at a pulsatile pressure of 25 mmHg starting immediately after retrieval until back-table preparation immediately before kidney transplantation.

Group 2 intervention group: the kidney will be placed on the Kidney Assist HMP device and perfused with oxygenated Belzers Machine Preservation Solution at a pulsatile pressure of 25 mmHg starting immediately after retrieval until back-table preparation immediately before kidney transplantation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Kidney graft function as measured by a 24-hour creatinine clearance at 1 year after transplantation

Key secondary outcome(s)
1. Delayed graft function (DGF) - DGF defined as the need for dialysis (excluding one time dialysis for hyperkalaemia or fluid overload) within the first 7 days after kidney transplantation and preceding the return of kidney function. Functional DGF defined as the absence of a decrease in the serum creatinine level of at least 10% per day for at least 3 consecutive days in the first week after transplantation, not including patients in whom acute rejection or calcineurin inhibitor toxicity is proven on biopsy.
2. Primary non function (PNF) defined as the permanent lack of function of the graft from time of transplantation until months post-transplant. This endpoint is determined post-hoc at 3 months post-transplant.
3. Biopsy proven acute rejection within first year post transplant.
4. Length of recipient hospital stay
5. Estimated glomerular filtration rate according to the 4-variable Modification of Diet in Renal Disease (MDRD) equation at 3 months, 6 months and 1 year after transplantation
6. 1 year graft (censored and uncensored for recipient death) survival
7. 1 year patient survival

Completion date
30/06/2018

Eligibility

Key inclusion criteria
Donors:
1. All potential consecutive Maastricht category III DCD donors aged 50 years or older from the collaborating donor regions

Recipient:
1. At least 18 years old
2. Listed for renal transplantation due to end stage renal disease
3. Willingness to comply with the protocol procedures for the duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
197

Key exclusion criteria
Donor:
1. An aortic patch too small for a reliable connection
2. Too many renal arteries preventing a safe connection

Recipient:
1. Multi-organ transplantation
2. Planned dual kidney transplantation
3. The recipient is unable or unwilling to give informed consent

Date of first enrolment
22/02/2015

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

Belgium

Netherlands

Study participating centre
University Hospitals Leuven
Leuven
Belgium
3000

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme (Grant number 305934 Work Package 4)

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	21/11/2020	23/11/2020	Yes	No