ISRCTN63852508 https://doi.org/10.1186/ISRCTN63852508

COPE-POMP: 'in house' pre-implantation oxygenated hypothermic machine perfusion reconditioning after cold storage versus cold storage alone in expanded criteria donor (ECD) kidneys from brain dead donors

Submission date
28/02/2014

Recruitment status
No longer recruiting

Registration date
09/04/2014

Overall study status
Completed

Last Edited
22/04/2021

Condition category
Surgery

[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 methods for storing and transporting kidneys for transplantation are to either store them in cold storage solution or to perfuse them with a cold perfusion solution on ice. It has been shown that machine perfusion preservation improves short term graft function, especially in kidneys donated by expanded criteria donors (ECD). Experimental models have shown that it is sufficient to perform machine perfusion immediately prior to implantation and reperfusion of the organ. This would also show a benefit to logistics, as kidneys would only need to be perfused at the transplantation center of the recipient. The aim of this study is to assess whether machine perfusion only immediately prior to implantation and after transport in cold storage solution will reduce damage, decrease ischemia-reperfusion injury and improve graft survival and function in ECD kidneys.

Who can participate?
Kidneys donated after brain death from donors fulfilling the United Network for Organ Sharing (UNOS) ECD criteria.

What does the study involve?
Two groups will be compared: a control group (static cold storage) and an interventional group (hypothermic oxygenated machine perfusion after static cold storage).

What are the possible benefits and risks of participating?
Short-term hypothermic oxygenated machine perfusion may be beneficial to static cold storage in ECD kidneys. In this study, two standard preservation methods are being compared.

Where is the study run from?
The trial will be carried out in academic hospitals with an active adult kidney transplant programme in Germany, Belgium, the Netherlands, United Kingdom and their donor hospitals. The lead center will be the University Hospital Essen, Germany.

When is the study starting and how long is it expected to run for?
December 2013 to July 2019

Who is funding the study?
European Union

Who is the main contact?
Professor Andreas Paul

Study website
http://www.cope-eu.org/work-packages/wp3

Contact information

Type(s)
Scientific

Contact name
Prof Andreas Paul

Contact details
Department of General, Visceral and Transplant Surgery
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A prospective, randomized, parallel group, single blinded, controlled, multi-center, non-paired superiority trial to compare the effect of short-term 'in house' oxygenated hypothermic machine perfusion preservation after static cold storage to static cold storage alone in transplantation of expanded criteria donor (ECD) kidneys donated after brain death

Acronym
COPE-POMP (Consortium for Organ Preservation in Europe - Pre-implantation Oxygenated hypothermic Machine Perfusion)

Study objectives
Short-term reconditioning using hypothermic oxygenated machine perfusion preservation following static cold storage and prior to reimplantation is superior to static cold storage alone in ECD kidneys.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the Faculty of Medicine, University of Duisburg-Essen, 25/09/2014, ref: 14-5783-BO

Study design
Prospective randomized parallel group patient-blinded controlled multi-center non-paired superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://cope-eu.org/

Health condition(s) or problem(s) studied
Machine perfusion preservation techniques for ECD kidneys

Interventions
ECD kidneys will be randomized to be preserved using either static cold storage alone or static cold storage followed by hypothermic oxygenated machine perfusion.

Group 1 - control group: the kidney wil be retrieved and stored in cold storage solution until back-table preparation and kidney transplantation are performed.

Group 2 - experimental group: the kidney will be placed in cold storage solution until arrival at the recipient's transplant center. Following back-table preparation the kidney will be placed on the Kidney Assist device to be perfused with cold oxygenated Belzer's Machine preservation solution until immediately before implantation.

The previous sponsor for this trial (up to 24/04/2014) was:
University Hospital Essen (Germany)
Hufelandstr. 55
Essen
45147
Germany
http://uk-essen.de/

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Graft survival after 1 year

Secondary outcome measures
1. Patient and graft survival at day 7, and at 3, 6 and 12 months after transplantation
2. Estimated glomerular filtration rate (eGFR) defined by the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation at days 7 and 14 and 3, 6 and 12 months after transplantation
3. Delayed graft function (DGF), defined as the need for dialysis within the first 7 days after transplantation and preceding the return of kidney function
4. Slow graft function (SGF) based on functional DGF (fDGF), 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 7 days after transplantation
5. Primary non-function (PNF), defined as the continued need for dialysis at 3 months after transplantation
6. Biopsy proven acute rejection incidence
7. Quality of life measures (EQ-5D-5L) at time of consent, 3 and 12 months
8. Health economic analysis: length of hospital stay, intensive care unit stay, requirement of dialysis
9. Incidence of hyperkalemia at 3, 6 and 12 months
10. Incidence of calcineurin inhibitor toxicity

Overall study start date
01/12/2013

Completion date
01/07/2019

Eligibility

Key inclusion criteria

Donors:
1. Kidneys from brain dead donors fulfilling the United Network for Organ Sharing ECD criteria

Recipient:
1. At least 18 years old.
2. Listed for renal transplantation due to end stage renal disease within one of the participating centers
3. The transplantation is the participant's first or re-transplantation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
262

Total final enrolment
262

Key exclusion criteria
Donor:
1. Kidney used for a multi-organ transplantation
2. Donor aged 85 or older
3. Donation after cardiac death
4. Kidney used for double-kidney transplantation within the same recipient

Recipient:
1. Simultaneous participation in another perfusion trial
2. Scheduled to undergo multi-organ transplantation
3. Planned dual-kidney transplantation
4. Both kidneys being transplanted within the same recipient
5. Is unable or unwilling to provide informed consent

Date of first enrolment
01/05/2014

Date of final enrolment
18/05/2018

Locations

Countries of recruitment

Belgium

England

Germany

Netherlands

United Kingdom

Study participating centre
Department of General, Visceral and Transplant Surgery
University Hospital Essen
Hufelandstr. 55
Essen
Germany
45147

Study participating centre
Oxford Transplant Centre
Oxford University Hospitals
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Study participating centre
University Hospitals Leuven
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Study participating centre
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Transplantation Surgery
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Groningen
Netherlands
9713

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
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Old Road
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United Kingdom
OX3 7LE

Sponsor type
University/education

Website
http://www.nds.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
European Union - Seventh Framework Programme (FP7) (grant number 305934 - Work Package 3)

Results and Publications

Publication and dissemination plan
Planned publication in high-Impact peer reviewed journal.

Intention to publish date
01/11/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	22/04/2021	Yes	No