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Clinical investigation to assess the safety and performance of the Organox Metra, for normothermic perfusion of livers, prior to transplantation and to compare with retrospective data from matched controls

Submission date
11/10/2012

Recruitment status
No longer recruiting

Registration date
27/11/2012

Overall study status
Completed

Last Edited
25/05/2018

Condition category
Surgery

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

Plain English Summary
Background and study aims
The OrganOx metra is an automated transportable device for preserving donated livers for transplantation. The aim of this study is to assess the safety and performance of the OrganOx Metra as an organ preservation method before liver transplantation.

Who can participate?
Patients aged 18 or older on the waiting list for liver transplantation

What does the study involve?
Participants receive liver transplants that have been preserved using the OrganOx metra device. The functioning of the transplanted liver and the patient survival rate are compared with the results from livers that were preserved using the conventional ice bucket method.

What are the possible benefits and risks of participating?
This study may demonstrate the safety and performance of the OrganOx metra as a medical device for the preservation of livers before transplantation. It is hoped that there will be benefits in terms of both the quality and quantity of livers available for transplantation. We believe that this would reduce the waiting time for liver transplantation and improve outcomes for patients. Liver transplant surgery carries a risk of significant complications, including bile duct complications, bleeding, blood clots, infection, memory and thinking problems, and failure or rejection of the donated liver. Using the OrganOx Metra does not increase the level of risk to the patient.

Where is the study run from?
Kings College Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2012 to December 2013

Who is funding the study?
OrganOx Ltd (UK)

Who is the main contact?
Dr Toni Day
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Contact information

Type(s)
Scientific

Contact name
Prof Nigel Heaton

Contact details
King's College Hospital
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ORG/NPL/001

Study information

Scientific Title
Non-randomised, open-label, single-arm, prospective clinical investigation to assess the safety and performance of the Organox Metra, for normothermic perfusion of livers, prior to transplantation and to compare with retrospective data from matched controls

Study hypothesis
To assess the safety and performance of normothermic perfusion as an organ preservation method prior to liver transplantation using the OrganOx Metra.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dulwich Research Ethics Committee, 19/07/2012

Study design
Non-randomised open-label single-arm prospective clinical investigation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
Liver transplant

Interventions
Treatment arm 1: livers transplanted after preservation on the OrganOx metra device, the methodology for current clinical practice for liver transplantation is observed.

Treatment arm 2: Retrospectively collected data from livers transplanted after preservation using the conventional ice bucket, the methodology for current clinical practice for liver transplantation is observed.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Graft survival at 30 days

Secondary outcome measures
1. Histological post-reperfusion biopsies (H&E and immunohistochemistry) 60 minutes after arterial reperfusion (before abdominal closure)
2. Markers of endothelial damage and pro-inflammatory cytokines (TNF, IL-6, vWF) (postoperative)
3. Markers of liver function (Bilirubin, Alkaline phosphatase, GGT, AST, creatinine (postoperative)
4. Six month magnetic resonance cholangiopancreatography (MRCP) appearances
5. Six month graft survival
6. Six month patient survival

Overall study start date
11/10/2012

Overall study end date
01/12/2013

Eligibility

Participant inclusion criteria
Organ inclusion criteria
1. Livers from male or female adult donors (18 years or greater)
2. Accepted for transplantation using current (standard and extended) criteria
3. Both heart-beating (DBD) and non-heart-beating (DCD) donor organs may be included

Recipient Inclusion criteria
1. Male or female, aged 18 years or older
2. On the waiting list for liver transplantation at Kings College Hospital, London.
3. Provided informed consent for participation in the study
4. Able and willing to comply with all study requirements (in the opinion of the investigator or nominated deputy)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Participant exclusion criteria
Organ exclusion criteria
1. Livers offered from a donor hospital that is located more than 3 hours travelling time (by road) of both Kings College Hospital and Oxford.
2. Donors in whom the liver is planned to be split.
3. Donor livers that would not be accepted under current (Kings College Hospital) criteria.
4. Livers taken from donors aged <18 years.
5. Donors with high donor serum Na+ (> 160 mmol/litre) at the time of liver retrieval.

Recipient Exclusion criteria
The participant may not enter the study if ANY of the following apply:
1. Not willing to, unable or not capable to provide informed consent
2. Recipients aged less 18 years

3. Undergoing transplant for fulminant hepatic failure
4. Undergoing re-transplantation.
5. Undergoing transplantation of other organ(s) in addition to the liver
6. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participant at risk by participating in the study, or may influence the result of the study, or the participants ability to participate in the study.
7. Not suitable for any other reason, in the opinion of the Investigator, to take part in the study.
8. Enrolled in clinical studies of other unlicensed therapy.
9. Participated in another research study involving an investigational product in the previous 12 weeks.
10. Pregnant or nursing mothers

Recruitment start date
11/10/2012

Recruitment end date
01/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
OrganOx Ltd (UK)

Sponsor details
c/o Dr Toni Day
Magdalen Centre
Oxford
United Kingdom
OX5 1TN

Sponsor type
Industry

Website
http://www.organox.com

ROR
https://ror.org/04fqe7a64

Funder(s)

Funder type
Industry

Funder Name
OrganOx Ltd (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	01/06/2016		Yes	No