ISRCTN00167887 https://doi.org/10.1186/ISRCTN00167887

Gaseous oxygen enrichment before implantation as a means of improving organ function in liver transplantation

Submission date 14/06/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/07/2011	**Overall study status** Completed	
Last Edited 19/08/2019	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
A major and increasing problem in liver transplantation is the shortage of donor livers, which forces the use of lower quality organs for transplantation (e.g. donor´s age over 65). New techniques are therefore needed to preserve donor livers before implantation. Treating the organs with oxygen gas (oxygenation) not only maintains the cell structures of the treated organ but also enables the repair of damaged structures. The aim of this study is to assess the effectiveness of short-term oxygenation (performed for 2 hours immediately before transplantation) in liver preservation to improve organ function especially during the critical first three days after transplantation.

Who can participate?
Patients over 18 years of age scheduled for their first liver transplantation

What does the study involve?
Participants are randomly allocated to one of two groups. For one group the donor liver is oxygenated for two hours before implantation. The other group receive standard care (cold storage of the donor liver without further treatment before implantation). Blood samples are taken daily for the first six days following surgery, at the day of discharge from the hospital and at each follow-up visit (every three months for up to three years). Complications reported by the participant are recorded at the day of discharge and at each follow-up visit. To assess the effectiveness of the treatment we measure blood values reflecting the quality of liver function, the duration of intensive care needed after surgery, and the rate of further transplants and deaths during the three months following transplantation.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital of Essen (Germany)

When is the study starting and how long is it expected to run for?
August 2011 to September 2013

Who is funding the study?
Deutsche Forschungsgemeinschaft (German Research Community) (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized controlled clinical trial to investigate oxygen persufflation as adjunct in liver preservation

Acronym
OPAL

Study objectives
Vascular oxygen persufflation of liver grafts in hypothermic condition performed for 2 hours prior to implantation maintains cell and organ integrity and function and also enables to some

extend the repair of damaged structures and restoration of cellular ion and signal homeostasis. Thus the rate and severity of early graft dysfunction events can be lowered and the viability of marginal quality grafts increased. The aforementioned effects have been shown in a large animal model. The safety of the procedure and its applicability to the human situation has already been demonstrated as well. This trial is designed as a final proof-of-concept study aiming to establish oxygen persufflation as valuable adjunct in clinical liver preservation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, Medical Faculty, University of Duisburg-Essen (Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen), 10/01/2011, ref: 09-4281

Study design
Single-center randomized controlled single-blind clinical proof-of-concept study with two parallel arms

Primary study design
Interventional

Secondary study design
Randomised parallel trial

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

Health condition(s) or problem(s) studied
Preservation and implantation of liver grafts

Interventions
In the treatment group donor livers will be subjected to 2 hours of venous systemic oxygen persufflation prior to implantation, while still being stored in ice cold preservation solution.

In the control group the standard preservation method will be applied (hypothermic storage without oxygen persufflation)

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure

Serum peak value of systemic aspartate aminotransferase during the first three days after transplantation

Secondary outcome measures
1. Death
2. Retransplantation within 3 months after implantation
3. Time of stay in intensive-care-unit
4. Hepatic tissue perfusion one hour after revascularization
5. Early onset of graft dysfunction (based on Quick´s value as well as the use of a refined scoring-system for initial graft function based on a multi-parameter [aspartate transaminase (AST), alanine aminotransferase (ALT), Quick and bilirubin] score according to Heise and co-workers

Overall study start date
01/08/2011

Completion date
30/09/2013

Eligibility

Key inclusion criteria
Patients:
1. Men and women beyond 18 years of age
2. Resident in Germany
3. Scheduled for first liver transplantation and graft already available
4. Patient is willing and able to attend regular follow up examinations
5. Written informed consent

Donor organs:
1. Donor grafts that are offered to the local transplant clinic for implantation, i.e. organ rescue offers
2. Donor age above 65

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
116

Key exclusion criteria

1. Listed as high urgency (HU)
2. Participation in this study at an earlier time
3. Simultaneous participation in other clinical trial
4. Present alcohol or drug abuse
5. Positive test for human immunodeficiency virus (HIV)
6. Pregnant or nursing

Date of first enrolment
01/08/2011

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Germany

Study participating centre
University of Duisburg-Essen
Essen
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45122

Sponsor information

Organisation
University Hospital Duisburg-Essen (Germany)

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Sponsor type
Hospital/treatment centre

Website
http://www.uni-due.de/index.shtml.en

ROR

https://ror.org/04mz5ra38

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft (MI 470/14-2)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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?
Protocol article	protocol	28/10/2011		Yes	No
Results article	results	16/08/2019	19/08/2019	Yes	No