

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

<b>Submission date</b> 14/06/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/08/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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?  
Prof. Dr. med. Andreas Paul  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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 extent 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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## 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  
Germany  
45122

## **Sponsor information**

**Organisation**  
University Hospital Duisburg-Essen (Germany)

**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, Deutsche Forschungsgemeinschaft (DFG), DFG

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
Germany

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	16/08/2019	19/08/2019	Yes	No
<a href="#">Protocol article</a>	protocol	28/10/2011		Yes	No