ISRCTN95672167 https://doi.org/10.1186/ISRCTN95672167

# Impact of iloprost on early graft viability after liver transplantation

| Submission date | Recruitment status |
|---|---|
| 31/07/2008 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 09/10/2008 | Completed |
| **Last Edited** | **Condition category** |
| 27/09/2017 | Injury, Occupational Diseases, Poisoning |

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Erik Bärthel

**Contact details**
Department of General Visceral and Vascular Surgery
University Hospital of Jena
Jena
Germany
07740

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## Study information

**Scientific Title**

Impact of iloprost on early graft viability after liver transplantation: a randomised controlled trial

## Study objectives
Improved graft viability under treatment with systemically administered prostacyclin analogue iloprost.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of Medical Faculty, Friedrich Schiller University of Jena (Ethik-Kommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät). Date of approval: 20/06/2006 (ref: 1765-04/06)

## Study design
Prospective randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Liver transplantation

## Interventions
A prospective, randomised, single-center study. Patients of the treatment group received 1 ng /kg body weight /min iloprost (BayerVital AG Berlin, Germany), systemically administered for 7 days post-liver transplantation, in contrast to the control (no treatment) population. Peak levels of transaminases (aspartate aminotransferase [ASAT]/alanine aminotransferase [ALAT]), factor V, quick's value, bile production and the indocyanine green plasma disappearance rate (ICG-PDR), were determined continuously. Furthermore, the arterial resistance index (RI) as parameter of liver perfusion as well as patient and graft survival were evaluated.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)

Iloprost

### Primary outcome measure
Incidence of primary graft dysfunction within 48 hours postoperatively.

### Secondary outcome measures
1. Rate of re-transplantation caused by initial graft non-function within 48 hours postoperatively
2. Time of hospitalisation (duration of follow-up depends on the circumstances of each patient)
3. Length of stay in intensive care unit (duration of follow-up depends on the circumstances of each patient)
4. Rate of complications due to biliary tract lesions within 1-year follow-up

### Overall study start date
01/09/2006

### Completion date
01/09/2008

## Eligibility

### Key inclusion criteria
1. Aged over 18 years, either gender
2. Full size orthotop liver transplantation

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80

### Key exclusion criteria
1. Circulatory instability
2. Noradrenaline doses >0.5 µg/kg body weight/min
3. Pregnancy
4. Known intolerance of iloprost

### Date of first enrolment
01/09/2006

### Date of final enrolment
01/09/2008

# Locations

### Countries of recruitment
Germany

### Study participating centre
**Department of General Visceral and Vascular Surgery**
Jena
Germany
07740

# Sponsor information

### Organisation
University Hospital of Jena (Universitätsklinikum Jena) (Germany)

### Sponsor details
Department of General Visceral and Vascular Surgery
Erlanger Allee 101
Jena
Germany
07740

### Sponsor type
Hospital/treatment centre

### Website
http://www.uniklinikum-jena.de

### ROR
https://ror.org/035rzkx15

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
University Hospital of Jena (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? |
|---|---|---|---|---|---|
| Results article | results of pilot study | 01/01/2012 | | Yes | No |