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# Impact of iloprost on early graft viability after liver transplantation

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 31/07/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 09/10/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 27/09/2017 | Injury, Occupational Diseases, Poisoning | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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

### Study type(s)
Treatment

### 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(s)
Incidence of primary graft dysfunction within 48 hours postoperatively.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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)

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

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
University Hospital of Jena (Germany)

# Results and Publications

## 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 |