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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

Contact name
Dr Erik Bärthel

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

Additional identifiers

Protocol serial number
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

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