Impact of iloprost on early graft viability after liver transplantation

Submission date	Recruitment status No longer recruiting	Prospectively registered		
31/07/2008		☐ Protocol		
Registration date 09/10/2008	Overall study status Completed	Statistical analysis plan		
		[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

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Contact details

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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)

lloprost

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