

Prospective randomised multicentre trial investigating liver preservation with Histidine-Tryptophan-Ketoglutarate (HTK) by simple aortic perfusion in comparison to aortic perfusion plus ex situ arterial flushing

Submission date 09/07/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2021	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2007-002 KKS

Study information

Scientific Title

Prospective randomised multicentre trial investigating liver preservation with Histidine-Tryptophan-Ketoglutarate (HTK) by simple aortic perfusion in comparison to aortic perfusion plus ex situ arterial flushing

Acronym

Perfusionsstudie

Study objectives

Main question of the trial:

Does Ischaemic Type Biliary Lesions (ITBL) occur less frequently in a liver preserved by aortic perfusion plus ex situ arterial flushing than in a liver preserved by simple aortic perfusion?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee (Landesärztekammer Rheinland-Pfalz) on the 27th April 2007 (ref: 837.364.05 [5462]). The ethics committees of all other trial centres have to approve the study before the centres could start with their trial participation.

NOTE: In this study dealing with liver transplantation, only the Central Region of the German Foundation for Organ Transplantation (Region Mitte der Deutschen Stiftung Organtransplantation) is recruiting. All other centres are "only" implanting the organs and making the follow-up.

Study design

Randomised, controlled, multicentre, parallel group, two-armed trial. The grafts will be delivered to the transplant centre in a blinded way.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Liver transplantation after preservation in brain-death organ donors

Interventions

Aortic in situ perfusion versus aortic in situ perfusion plus arterial back-table ex situ flushing.

At the beginning of the process of abdominal dissection, a tube is placed into the abdominal aorta (or into a common iliac artery). The perfusate (HTK [Histidine-Tryptophan-Ketoglutarate] solution) is connected to this tube. Usually a perfusion pressure of 100 to 150 cm water column is applied which is realised by elevation of the plastic bag containing the fluid. When the liver is dissected free in order to be retrieved the perfusion is started. At least 8000 ml of solution have to be used.

In the control group the approach of preservation is stopped at this point, the liver is retrieved, put into plastic bags containing preservation solution and is forwarded to the transplant centre of the respective patients to whom the graft was allocated by Eurotransplant.

In the case of additional ex-situ arterial perfusion, the liver is retrieved and placed into an ice water dish. There all branches of the hepatic artery are tied, a cannula is placed into the artery at its origin and the ex-situ perfusion is performed. For ex-situ perfusion, 300 ml of the perfusate at a pressure of 100 cm water column is used. After that procedure, the graft is forwarded in the identical way as for non-ex-situ perfused grafts.

The transplantation itself is going to be performed at the discretion of the respective centre. Follow-up will be six months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Histidine-Tryptophan-Ketoglutarate (HTK)

Primary outcome(s)

Rate of ITBL six months after transplantation.

Key secondary outcome(s)

1. Rate of ITBL or death within six months after transplantation
2. Parenchymal function following transplantation
3. Documentation and analysis of adverse events

All secondary outcomes are measured within six months after transplantation.

Completion date

31/10/2009

Eligibility

Key inclusion criteria

For the graft:

1. Liver graft retrieved in the Central Region of the German Foundation for Organ Transplantation (Region Mitte der Deutschen Stiftung Organtransplantation [DSO])
2. Donor 18 - 80 years
3. Graft allocation to a participating centre

For the recipient

1. Informed consent
2. Age 18 - 80 years
3. Standard criteria for liver transplantation (e.g. liver dysfunction because of cirrhosis, carcinoma)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

242

Key exclusion criteria

For the graft:

1. Liver cirrhosis
2. Liver intoxication
3. Liver dysfunction
4. Liver trauma
5. Graft not transplantable (decision according to Standard Operating Procedures [SOP])
6. Liver split

For the recipient:

1. Standard criteria for liver transplantation

Date of first enrolment

09/07/2007

Date of final enrolment

31/10/2009

Locations

Countries of recruitment

Germany

Study participating centre

Director of Transplantation and Hepatobiliopancreatic Surgery

Mainz

Germany

55131

Sponsor information

Organisation

Johannes Gutenberg University of Mainz (Germany)

ROR

<https://ror.org/023b0x485>

Funder(s)

Funder type

University/education

Funder Name

Johannes Gutenberg University of Mainz (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		26/06/2017	29/10/2021	Yes	No