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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2007	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 (Landesarztekammer 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 Transplantion (Region Mitte der Deutschen Stiftung Organtransplantation) is recruting. 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

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 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 is 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 measure
Rate of ITBL six months after transplantation.

Secondary outcome measures
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.

Overall study start date
09/07/2007

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 Transplantion (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

Age group
Not Specified

Sex
Not Specified

Target number of participants
126 - 174 depending on the result of the interim

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
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Sponsor information

Organisation
Johannes Gutenberg University of Mainz (Germany)

Sponsor details
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Sponsor type
University/education

Website
http://www.klinik.uni-mainz.de

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
University/education

Funder Name
Johannes Gutenberg University of Mainz (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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