

# 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

<b>Submission date</b> 09/07/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> 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?
<a href="#">Results article</a>		26/06/2017	29/10/2021	Yes	No