ISRCTN69350312 https://doi.org/10.1186/ISRCTN69350312

HEGPOL: Randomised, placebo controlled, multicenter, double-blind clinical trial to investigate hepatoprotective effects of glycine in the postoperative phase of liver transplantation

Submission date 29/06/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/10/2004	**Overall study status** Completed	
Last Edited 24/08/2009	**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
22 00 16

Study information

Scientific Title

Acronym
HEGPOL

Study objectives
Added 24/08/09:
Kupffer cell-dependent ischemia / reperfusion (I/R) injury after liver transplantation is still of high clinical relevance, as it is strongly associated with primary dysfunction and primary nonfunction of the graft. Glycine, a non-toxic, non-essential amino acid has been conclusively shown in various experiments to prevent both activation of Kupffer cells and reperfusion injury. Based on both experimental and preliminary clinical data this study protocol was designed to further evaluate the early effect of glycine after liver transplantation.

As of 24/08/09 this record has been extensively updated. All updates can be found in the relavent field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised double blind placebo controlled parallel group trial

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 (LTX)

Interventions
Verum group receives intravenous 250 ml glycine-solution (4.4%), starting prior to reperfusion of liver transplant during surgery and once daily during the first week after LTX.
Placebo group receives intravenously 250 ml Aqua ad injection.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Added 24/08/09:
1. Peak levels of both aspartat-amino-transaminase (AST) and alanine-amino-transaminase (ALT) as surrogates for the progression of liver related injury
2. Graft and patient survival up to 2 years after transplantation

Secondary outcome measures
Added 24/08/09:
1. Effect of glycine on liver injury based on liver biopsy immediately after re-arterialisation (according to pathological report)
2. Total blood flow in portal vein and common hepatic artery 1 hour after reperfusion
3. Graft injury based on both AST and ALT serum levels (area under the curve [AUC])
4. Incidence of early graft failure based on peak of transaminases or clotting factor support
5. Early onset of graft dysfunction based on Quick's value
5. Serum bilirubin (AUC)
7. CyA-induced nephrotoxicity based on retention parameters during the first eight days after transplantation (AUC)

Overall study start date
01/04/2006

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Liver transplant recipients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Added 24/08/09: 130

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/04/2006

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Germany

Study participating centre
Coordination Centre for Clinical Trials (KKS)
Heidelberg
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Sponsor information

Organisation
University of Heidelberg (Germany)

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Sponsor type
University/education

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
University/education

Funder Name
University of Heidelberg (Germany) - Medical faculty

Funder Name
Novartis Pharma (Germany) - unrestricted grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	17/08/2005		Yes	No