ISRCTN16660149 https://doi.org/10.1186/ISRCTN16660149

Risk factors for adverse cardiovascular events in liver transplantation

Submission date 04/02/2025	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 06/02/2025	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 06/02/2025	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Liver cirrhosis is a terminal and irreversible stage of chronic hepatic disease. The etiology is various and includes alcohol, infections, carcinoma, medicaments and toxins, immune disease, cholestasis, metabolic causes, sarcoidosis etc. Therapy in end-stage liver disease is liver transplantation. A cadaveric orthotopic transplantation liver graft is a liver transplant where the donor organ (the graft) is taken from a deceased person (cadaver) and placed in the recipient's body in the same anatomical position as their native liver, replacing it completely. The donor and recipient's factors influence the transplantation procedure and its outcome, affecting post-transplant morbidity and mortality. Liver transplantation poses a high risk for cardiovascular complications and cardiac death. It can reverse certain pathologic states induced by hepatic disease but it can also lead to acute decompensation and cardiac death. Current studies show different incidences of cardiovascular adverse events during and after liver transplantation, without connecting donor-recipient traits to these events. This study aims to find the incidence of adverse cardiovascular events during orthotopic liver transplantation and during early posttransplant time and to establish which factors, donor and recipient, contribute to these adverse events. Furthermore, the study will create a simple grading scale that allows us to predict the incidence of severe cardiovascular adverse events in this vulnerable group of patients.

Who can participate?
All patients aged 18 years old and over who were admitted to University Hospital Merkur, Zagreb, Croatia for liver transplants between 2013 and 2015

What does the study involve?
The medical records of patients who are admitted for liver transplantation are reviewed, including their charts during and after surgery. Information about the donors is obtained from Eurotransplant donor reports. Scoring systems will be used to model the study outcomes.

What are the possible benefits and risks of participating?
The overall benefit of the study is for further patients who will be undergoing liver transplantation in future. Since this is an observational, non-intervention retrospective chart review study, there is no risk for participants.

Where is the study run from?
University Hospital Merkur (Klinička bolnica Merkur)

When is the study starting and how long is it expected to run for?
January 2013 to July 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Nataša Višković Filipčić, MD., natasa.viskovic-filipcic@agram-bolnica.hr, natashav7@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Risk factors associated with adverse cardiovascular events during orthotopic liver transplantation and during early posttransplant time

Acronym
ACV-OLT

Study objectives
The incidence of adverse cardiovascular events during orthotopic liver transplantation and early posttransplant time is less than 5%.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/12/2014, Ethics Committee of University Hospital Merkur (Zajčeva 19, Zagreb, 10000, Croatia; +385 1 2353 801; eticko.povjerenstvo@kb-merkur.hr), ref: 0311-13652

Study design
Single-center 3-year observational study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Adverse cardiovascular events in patients eligible for liver transplantation during the procedure itself and early posttransplant time

Interventions
Medical records of patients admitted for liver transplantation and their intraoperative and postoperative charts are examined. Donor data are acquired from Eurotransplant donor reports. Any subsequent scores are calculated according to official scoring systems (MELD, DRI).

Intervention Type
Procedure/Surgery

Primary outcome(s)

To establish the incidence of adverse cardiovascular events in a group of patients with liver transplantation during the transplant procedure and early posttransplant time (30 days) measured using data collected from patient medical records at one time point

Key secondary outcome(s))
The following secondary outcome measures are evaluated measured using data collected from patient medical records at one time point:
1. Donor and recipient characteristics in a subgroup of patients with severe adverse cardiovascular events
2. The risk of adverse cardiovascular complications in the subgroup of patients with severe adverse cardiovascular events defined using a simple grading scale
3. To create a simple scale based on donor and recipient characteristics, used for risk assessment

Completion date
10/07/2016

Eligibility

Key inclusion criteria
1. Patients admitted and undergoing liver transplantation in UH Merkur, Zagreb, Croatia
2. 18 years of age and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
291

Key exclusion criteria
1. Age less than 18 years
2. Liver re-transplantation
3. Acute liver failure
4. Living donor liver transplantation
5. Multiorgan transplantation

Date of first enrolment
10/08/2015

Date of final enrolment
10/07/2016

Locations

Countries of recruitment
Croatia

Study participating centre
University Hospital Merkur
Zajčeva ulica 19
Zagreb
Croatia
10000

Sponsor information

Organisation
Klinička bolnica Merkur

ROR
https://ror.org/01b6d9h22

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and/or analysed during the current study are not expected to be made available due to transplant laws and regulations

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes