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Understanding the effects of a TIPS procedure on heart function

Submission date
10/07/2025

Recruitment status
No longer recruiting

Registration date
27/08/2025

Overall study status
Completed

Last Edited
27/08/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A transjugular intrahepatic portosystemic shunt (TIPS) procedure is used to lower high blood pressure in the veins of the liver, which can occur in people with liver cirrhosis. TIPS creates a new pathway that allows blood to bypass the liver and flow directly to the heart. As a result, the heart suddenly has to handle more blood than usual. In some cases, this extra strain can lead to heart failure, which may contribute to deaths after the procedure. This study aims to find out how the heart is affected before and after a TIPS procedure. We use cardiovascular magnetic resonance (CMR), which is the gold standard for measuring the size and function of the heart. Unlike standard heart ultrasound (echocardiography), CMR provides more detailed information about the heart's structure.

Who can participate?
Patients with liver cirrhosis and portal hypertension who underwent cardiac evaluation before TIPS Implantation

What does the study involve?
Participants undergo a cardiac MRI scan before and 48 hours and 3 months after TIPS implantation.

What are the possible benefits and risks of participating?
Patients receive a detailed report about how their heart functions after the TIPS procedure. This information can help with their further medical care. In addition, by taking part in the study, patients actively contribute to improving medical knowledge and helping future patients with similar conditions.
MRI is in general a safe imaging technique that does not use radiation. However, certain risks must be considered. People with metal implants (like pacemakers) are excluded from the study as the strong magnetic field can interfere with or move metal objects. Patients receive a contrast agent (gadolinium), which is generally safe but can cause allergic reactions or, in rare cases, problems in people with poor kidney function, therefore, patients with severely reduced kidney functions did not receive contrast agents. The MRI machine is loud and enclosed, which can cause discomfort or claustrophobia in some patients. Overall, MRI is considered low-risk when proper safety checks are performed.

Where is the study run from?
Charité Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
October 2017 to June 2023

Who is funding the study?
Charité Universitätsmedizin Berlin (Germany)

Who is the main contact?
Prof. Dr. Jeanette Schulz-Menger, jeanette.schulz-menger@charite.de

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Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3000283

Study information

Scientific Title
Cardiac MRI evaluation on cardiac function and tissue in patients with liver cirrhosis compared to healthy volunteers and during follow-up after transjugular intrahepatic portosystemic shunt implantation

Acronym
TIPS-CMR

Study objectives
Impact of transjugular intrahepatic portosystemic shunt (TIPS) on cardiac morphology, function and tissue properties

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/12/2017, Charité Ethics Committee (Charitéplatz 1, Berlin, 10117, Germany; 030 /450-517222; ethikkommission@charite.de), ref: EA1/231/17

Study design
Single-center non-interventional study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Liver cirrhosis and portal hypertension

Interventions
Analysis of cardiac MRI in patients with liver cirrhosis and portal hypertension evaluated for transjugular intrahepatic portosystemic shunt (TIPS): pre-procedure assessment and short- and long-term follow-up after TIPS placement (48 hours and 3 months after TIPS implantation).

Intervention Type
Other

Primary outcome measure
Left and right ventricle dimension measured using cardiac MRI before and 48 h and 3 months after TIPS implantation

Secondary outcome measures
Left and right ventricle function, native T1-time, T2-time, extracellular volume (ECV) and fibrosis on late gadolinium enhancement (LGE) images measured using cardiac MRI before and 48 h and 3 months after TIPS implantation

Overall study start date
01/10/2017

Completion date
23/06/2023

Eligibility

Key inclusion criteria
Patients with liver cirrhosis and confirmed portal hypertension with indication for TIPS procedure (refractory ascites or gastrointestinal variceal bleeding)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Total final enrolment
45

Key exclusion criteria
General contraindications to cardiac MRI (e.g. claustrophobic, metal implants)

Date of first enrolment
01/02/2018

Date of final enrolment
30/07/2022

Locations

Countries of recruitment
Germany

Study participating centre
HELIOS Hospital Berlin-Buch
Schwanebecker Chaussee 50
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Sponsor information

Organisation
Charité - Universitätsmedizin Berlin

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charité – Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/08/2025

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be stored in a non-publicly available repository (Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center, a joint cooperation between the Charité Medical Faculty and the Max-Delbrueck Center for Molecular Medicine)

IPD sharing plan summary
Stored in non-publicly available repository