

Understanding the effects of a TIPS procedure on heart function

Submission date 10/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/08/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
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Sponsor information**Organisation**

Charité - Universitätsmedizin Berlin

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

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