

Characterization of critically ill patients with severe bacterial infections using cardiovascular MRI

Submission date 10/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cardiomyopathy is the name given to a condition that makes it hard for the heart to pump blood effectively. Sepsis occurs when there is an overreaction of the body to fight infection with chemicals released into the blood affecting major organs. Sepsis-induced cardiomyopathy (SIC) is a common condition that occurs in 30-50% of patients with severe sepsis and septic shock. Until today there has been no scientific study on SIC utilizing cardiac MRI. Cardiac MRI represents a unique tool with abilities to assess not only cardiac function but also structural changes of the heart muscle such as edema, inflammatory processes and intramyocardial development of cardiac scars.

In this pilot study we want to assess functional and structural changes of the heart muscle in patients with septic shock using cardiac MRI. Results of the analysis could help to understand the mechanism of SIC and to develop clinical strategies to prevent and treat SIC in the future.

Who can participate?

Adult patients with septic shock.

What does the study involve?

All participants receive heart a MRI scan 24-72 hours after their peak of septic shock which is identified by peak dose of blood-pressure elevating norepinephrine medication. All participants receive treatment for their septic shock as usual.

What are the possible benefits and risks of participating?

Participants might benefit from earlier detection of heart problems using MRI compared to alternative routine techniques such as ultrasound. During the MRI scan, participants receive a standard dose of contrast medium that in rare occasions can cause allergic reactions. However, there are no study-associated side effects that exceed those of a regular MRI scan.

Where is the study run from?

HELIOS Hospital Berlin-Buch (Germany)

When is the study starting and how long is it expected to run for?

December 2015 to October 2019

Who is funding the study?

The cost of this study will be funded by the research group itself through university-affiliated research grants. Additionally, grant support has been given by Deutsche Herzstiftung e.V. (Grant number F/48/15)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Characterization of critically ill patients with septic shock and sepsis-associated cardiomyopathy using cardiovascular MRI – a pilot study

Acronym

CISS

Study objectives

Severe bacterial infections can affect the entire human body, which is called sepsis. It is known that these infections can also affect the function of the heart. In this study we hypothesized that changes of the heart muscle structure such as edema and inflammation can be detected in these critically ill patients using cardiovascular MRI. In detail, we hypothesized that myocardial T2 times are elevated in patients with severe sepsis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/12/2015, Charité University Medicine Berlin Ethics Board (Ethikkommission Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany; +49-30-450 517 222; ethikkommission@charite.de), ref: EA1/311/15

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

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

Sepsis-associated cardiomyopathy in septic shock

Interventions

Participants receive one cardiac MRI during septic shock, specifically between 24 and 72 hours after peak dose of norepinephrine. MRI protocol includes cardiac function assessment using cine imaging and myocardial tissue differentiation using native T1 and T2 mapping as well as the contrast-enhanced techniques late gadolinium enhancement and extracellular volume quantification. Additionally, follow-up cardiac ultrasounds are performed 48 and 96 hours after the MRI scan.

Intervention Type

Device

Drug/device/biological/vaccine name(s)

1. Cardiac MRI 2. Cardia ultrasound

Primary outcome measure

Mean myocardial T2 time measured using MRI at 24-72 hours after peak of norepinephrine

Secondary outcome measures

1. Left ventricular ejection fraction measured using MRI at 24-72 hours after peak of norepinephrine
2. Myocardial T1 time measured using MRI at 24-72 hours after peak of norepinephrine
3. Right ventricular ejection fraction measured using MRI at 24-72 hours after peak of norepinephrine
4. Left ventricular ejection fraction measured using echocardiography at 48 and 96hours after the MRI scan
5. Late gadolinium enhancement measured using MRI at 24-72 hours after peak of norepinephrine

Overall study start date

08/12/2015

Completion date

31/10/2019

Eligibility**Key inclusion criteria**

Septic shock requiring catecholamine treatment despite sufficient fluid resuscitation

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

15

Total final enrolment

15

Key exclusion criteria

1. Any absolute contraindication for MRI
2. Chronic renal failure with GFR < 30 ml/min/m² at time of inclusion (with the exception of patients on dialysis)
3. Myocardial infarction < 6 months before inclusion
4. Previously known LVEF < 40% at inclusion

Date of first enrolment

01/04/2016

Date of final enrolment

31/08/2019

Locations

Countries of recruitment

Germany

Study participating centre

HELIOS Hospital Berlin-Buch

Schwanebecker Chaussee 50

Berlin

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Sponsor information

Organisation

Helios Hospital Berlin-Buch

Sponsor details

Charité Berlin-Buch/HELIOS Hospital Berlin-Buch

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Sponsor type

University/education

Website

<http://www.cmr-berlin.org>

ROR

<https://ror.org/05hgh1g19>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Funder Name

Deutsche Herzstiftung e.V.

Results and Publications

Publication and dissemination plan

We are intending to publish at least one research article in a high-ranking peer-reviewed journal, such as JCMR (impact factor 5.1)

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to reasons of data protection laws in Germany. However, upon request methodology and data set structure can be shared.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/05/2022	23/05/2022	Yes	No