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

Submission date	Recruitment status	[_] Prospectively registered
10/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/07/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/05/2022	Circulatory System	

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 overereation 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 unqiue 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 Herzstifung 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 (Ethikommission 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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
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

Completion date
31/10/2019

Eligibility

Key inclusion criteria
Septic shock requiring catecholamine treatment despite sufficient fluid resuscitation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

Germany
13125

Sponsor information

Organisation
Helios Hospital Berlin-Buch

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

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