

# Differences in the quantity of fluid detected in pleural and pericardial space by cardiovascular magnetic resonance between healthy subjects and subjects with inflammatory heart disease

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<b>Registration date</b> 28/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/02/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The appearance of a small amount of pericardial and pleural fluid (fluid around the heart and lungs) seems to be a frequent finding in routine cardiovascular magnetic resonance (CMR) scans. It seems to be related to inflammation, but data are conflicting. In routine CMR small pericardial and pleural effusion are detectable in patients who meet all CMR criteria for myocardial (heart muscle) inflammation as well as in patients without any signs of myocardial inflammation. The findings were detectable in healthy volunteers who were participating in other trials. Currently, no systemic analysis exists studying these effusions. The main aim of this study is to better understand the occurrence of pleural and pericardial effusions in healthy volunteers and in patients with suspected inflammatory heart disease, especially if the traditional CMR criteria of myocardial inflammation are only partially fulfilled. The other aims are to assess the potential impact of quantification of these effusions on decision making in suspected myocardial inflammation, and the changes of pericardial and pleural effusion in premenopausal women across the menstrual cycle.

### Who can participate?

Patients with suspected inflammatory heart disease and healthy premenopausal women

### What does the study involve?

Healthy premenopausal women are asked to undergo a clinical examination, blood sampling and CMR scan without contrast media twice during different phases of their menstrual cycle. Changes of pericardial and pleural effusion are assessed and a cut-off value for "normal" amounts of these fluids is established. Patients with suspected cardiac inflammation who require CMR examination are asked to participate, and if willing, CMR data and blood samples, as well as dedicated clinical data, are collected.

What are the possible benefits and risks of participating?

There is no direct benefit expected for the participants. A standard blood sample is collected and there are possible risks: infection, irritation and warming of the puncture site may occur.

Where is the study run from?

HELIOS Clinic Berlin-Buch (Germany)

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

April 2015 to December 2023

Who is funding the study?

Charité – Universitätsmedizin Berlin (Germany)

Who is the main contact?

1. Prof. Jeanette Schulz-Menger

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2. Dr Agnieszka Töpfer

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## Contact information

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## Additional identifiers

### Protocol serial number

SERO PRO (internal study protocol name)

## Study information

### Scientific Title

Prevalence and characteristics of pleural and pericardial fluid in subjects with and without myocardial inflammation as detected using cardiovascular magnetic resonance imaging

### Study objectives

The study rationale is to analyze the frequency of occurrence of pleural and pericardial fluid deposits in humans and to get a better understanding of their relevance in cases of myocardial inflammatory disease.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 02/03/2016, Ethics board at Charité University Medicine Berlin, Campus Mitte (Ethikkommission, Ethikausschuss 1 am Campus Charite -Mitte, Chariteplatz 1, 10117 Berlin; Tel: +49 (0)3045051722; Email: ethikkommission@charite.de), ref: EA1/054/16

### Study design

Observational prospective cohort study

### Primary study design

Observational

### Study type(s)

Diagnostic

### Health condition(s) or problem(s) studied

Myocardial inflammatory disease

### Interventions

1. Cardiac MRI scan to detect myocardial inflammation at the beginning of the study (with contrast media for patients, without contrast media for healthy subjects), second cardiac MRI scan for female subjects in accordance to the phase of the menstrual cycle, maximal two MRI examinations during the study
2. Blood sampling once during the study
3. Follow up – on the basis of a questionnaire form up to 5 years

### Intervention Type

Other

### **Primary outcome(s)**

1. Presence of pleural and pericardial fluid deposits assessed using cardiac MRI scan at the baseline examination
2. Markers of inflammation measured using laboratory tests (WBC and c-reactive protein, hs-troponin) and MRI (standard parameters of myocardial inflammation: edema, late and early gadolinium enhancement) at baseline

### **Key secondary outcome(s)**

1. Presence of pleural and pericardial fluid deposits assessed using cardiac MRI scan in subjects without any sign of inflammation and in healthy subjects at baseline and in accordance to the phase of the menstrual cycle
2. The amount (measured in milliliters) of pleural and pericardial fluid detected by MRI in premenopausal women in different (follicular or luteal) phases of the menstrual cycle
3. Quantification (in milliliters) of small amounts of pleural and pericardial fluid by semiautomated threshold method in MRI DICOM data at luteal and follicular phase of menstrual cycle
4. Development of heart failure, hospitalizations for cardiovascular reasons, death, assessed using standard questionnaire form up to 5 years

### **Completion date**

31/12/2023

## **Eligibility**

### **Key inclusion criteria**

1. Patients with suspected inflammatory heart disease:  
Clinical indication for MR exam with late gadolinium enhancement
2. Healthy premenopausal women:  
MR exam without contrast media

### **Participant type(s)**

Mixed

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Any contraindication for MR exam
2. Any known pericardial or pleural disease
3. Any known malignant disease in the last 5 years
4. Pregnancy

### **Date of first enrolment**

03/02/2016

**Date of final enrolment**

28/02/2018

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

**HELIOS Clinic Berlin-Buch**

Schwanebecker Chaussee 50

Berlin

Germany

13125

## Sponsor information

**Organisation**

Charité University Medicine Berlin

**ROR**

<https://ror.org/001w7jn25>

## Funder(s)

**Funder type**

University/education

**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**

Data stored in anonymized form: DICOM-Data from CMR examination, the analysis of the CMR DICOM data, laboratory and questionnaire data stored in a study repository „agcmrt“.

**IPD sharing plan summary**

Stored in repository