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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

Submission date
17/07/2019

Recruitment status
No longer recruiting

Registration date
28/08/2019

Overall study status
Completed

Last Edited
08/02/2023

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Töpper
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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
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
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

Secondary outcome measures
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 mililiters) 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

Overall study start date
01/04/2015

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

Age group
Adult

Sex
Both

Target number of participants
300

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
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Sponsor information

Organisation
Charité University Medicine Berlin

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Sponsor type
University/education

Website
www.cmr-berlin.org

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

Publication and dissemination plan
Results of this study shall be published in a high-ranking peer-reviewed journal.

Intention to publish date
01/09/2019

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