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Heart function analysis in patients with arrhythmogenic cardiomyopathy

Submission date
07/09/2018

Recruitment status
No longer recruiting

Registration date
04/10/2018

Overall study status
Completed

Last Edited
22/01/2020

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
Arrhythmogenic cardiomyopathy (AC) is an inherited disease that can cause sudden cardiac death (SCD). Cardiac involvement is characterised by heart muscle cell loss. This leads to an enlarged heart, predominantly in the right ventricle (RV), which can then progress to heart failure. Patchy cell loss in the heart wall can cause electrical instability, which manifests as ventricular arrhythmia, which increases the risk of sudden death. The treatment is based on anti-arrhythmic medication and insertion of an implantable cardioverter defibrillator (ICD) , which protects from SCD in case of ventricular arrhythmia. The treatment for heart failure depends on the progress of the disease. In some cases a heart transplant is needed.
Cardiac MRI, the gold standard for RV analysis is not suitable for patients with ICD and echocardiography is often inadequate for this task. Regardless, disease progression still needs to be analysed.
Recent developments in CT imaging and image analysis have changed the options. CT scanning of the heart can now be performed with very low irradiation to the patient (less than 3 mSv). Our research team has developed a new model to measure heart volume and wall deformation using cardiac CT. The aim of this study is to assess ventricular volume and heart function using cardiac CT in AC patients with ICD to follow-up the progress of the disease.

Who can participate?
Adult patients from the tertiary care centre in Linköping University Hospital, Sweden, with a definite diagnosis of AC and implanted ICD.

What does the study involve?
Participants will undergo an examination of their heart using a CT scan, along with additional standard clinical follow-up echocardiography. For patients older than 60, blood samples will be taken to check kidney function.

What are the possible benefits and risks of participating?
The benefits are an increased ability to detect disease progression more accurately, in order to optimise the treatment to prevent the development of heart failure.
During the CT scan examination, the patient receives intravenous contrast. This could harm kidney function, particularly if an individual already has marginal kidney disease. A blood test is

done prior to CT scan to safeguard. Any time a venipuncture is performed, there is a risk of a haematoma.

Where is the study run from?
University Hospital of Linköping (Sweden)

When is the study starting and how long is it expected to run for?
December 2017 to December 2019]

Who is funding the study?
Hjärt-Lungfonden (Sweden)

Who is the main contact?
Meriam Åström Aneq
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ARVC och plötslig hjärtdöd

Study information

Scientific Title
Evaluation of ventricular function in patients with arrhythmogenic cardiomyopathy using multimodality imaging

Study objectives
Arrhythmogenic cardiomyopathy (AC) is an hereditary heart disease characterised by myocardial cell loss and fibrosis resulting in electrophysiological abnormalities and potentially fatal

arrhythmias, as well as contractile dysfunction of the right (RV) and left ventricles (LV). The treatment of AC is based on antiarrythmic therapy and the insertion of an implantable cardioverter defibrillator (ICD), which means that the assessment of the heart by cardiac magnetic resonance (CMR) not suitable. We use a new software on cardiac CT to track and quantify global and segmental changes in the ventricular function in AC patients with an ICD. We hypothesise that this new software on cardiac CT could help following the progress of disease to adjust the treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical board in Linköping (EPN), 21/03/2018, 2018/35-31

Study design
Observational prospective single-centre case series

Primary study design
Observational

Secondary study design
Case series

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
Arrhythmogenic cardiomyopathy

Interventions
Patients fulfilling definite Task Force Criteria for AC carrying an ICD undergo cardiac CT for heart function analysis. The study examination includes CT-scanning of the heart. A radiology technician performs the CT scan. During the test, the patient is lying on a table that is moved through the opening of the CT scanner. The examination takes 8-10 minutes. For patients older than 60 years old, renal function is checked via a blood sample to safeguard the use of iodine contrast.

Intervention Type
Other

Primary outcome measure
Assessment of the right and left ventricular volume and function, assessed using time-resolved CT scanning of the heart at the time of the scan

Secondary outcome measures
Software ability to detect regional, focal ventricular abnormalities in AC patients with ICD, assessed using a software that detects myocardial “pixels” and calculates the changes during the heart cycle at the time of the scan

Overall study start date
16/12/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Referred for diagnostic cardiac CT
2. Fulfil definite Task Force Criteria for arrhythmogenic cardiomyopathy
3. Implantable cardioverter defibrillator
4. Aged 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
All patients at Linköping hospital with definite AC diagnosis and an ICD are included.

Key exclusion criteria
1. Renal insufficiency
2. Pregnant women

Date of first enrolment
02/05/2018

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
Sweden

Study participating centre
University hospital of Linköping
Universitetssjukhuset
Linköping
Sweden
58185

Sponsor information

Organisation
University Hospital of Linköping

Sponsor details
Dept of Clinical Physiology
Institute of Medicine and Health Care
Linköping
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58185

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05h1aye87

Funder(s)

Funder type
Not defined

Funder Name
Hjärt- lungfonden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr M. Åström Aneq. meriam.astrom.aneq@regionostergotland.se. Measurements of heart volume and wall strain will be available by the end of the recruitment of patients and analysis of data, planned on 31/05/2019. Patients sign a consent that the CT measurements will be used for publication. All measurements are anonymised.

IPD sharing plan summary

Available on request