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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
Dr Meriam Åström Aneq

### Contact details
Dpt of Clinical physiology
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# Additional identifiers

### Protocol serial number
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

### Study type(s)
Diagnostic

### 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(s)
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

### Key secondary outcome(s))
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

### 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

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
All

**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

**ROR**
https://ror.org/05h1aye87

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Hjärt- lungfonden

# Results and Publications

### 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |