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Right heart function in patients with arrhythmogenic right ventricular cardiomyopathy

Submission date
09/03/2017

Recruitment status
No longer recruiting

Registration date
17/03/2017

Overall study status
Completed

Last Edited
18/02/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Arrhythmogenic right ventricular cardiomyopathy (ARVC) is a rare disease that affects the heart muscle. It is an inherited condition that is passed on through families. ARVC causes the heart muscle to break down and become replaced with fat and scar tissue. This causes the different chambers of the heart (ventricles) to become thin and stretched making the heart unable to pump blood properly. This causes abnormal heart beats (arrhythmia), heart palpitations (sudden beating), fainting, breathlessness, and even carries a risk of sudden death. Cardiovascular magnetic resonance imaging (CMR) (a scan that uses magnetic fields and radio waves to make a detailed image of the heart) is considered the best way for measuring right ventricular (RV) volume due to its ability to see the entire RV. However, measuring how well the RV functions (works) is based on seeing and scoring the wall motion which can be subjective. Recent research has developed new models for measuring RV such as using speckle-tracking. This is an established technique that is used to measure tissue velocity (speed and direction) and deformation (strain) using the natural speckle pattern in heart muscle during a scan. The method has been adapted into the CMR and is promoted as “feature tracking” which can be applied to measuring the left ventricular walls. However, as the heart changes due to ARVC and the challenges using software to track the changes, there is question if this new method is able to accurately predict ARVC. The aim of this study is to analyse the RV function using CMR-feature tracking in patients with ARVC to see if it could detect changes in wall deformation (strain) and beating which could then predict the occurrence of arrhythmia in these patients.

Who can participate?
Adults who are diagnosed with ARVC and healthy participants with no family history of early heart disease.

What does the study involve?
All participants undergo a CMR with feature tracking. This includes a full body scan for 30-40 minutes. Participants with ARVC also undergo non-invasive tests that records how well their hearts are working. The images from the CMR are compared between participants with ARVC and health controls to see how well the CMR with featured tracking is able to differentiate

between these two groups. Those with ARVC also undergo more non-invasive heart tests. Participants with ARVC are followed with yearly outpatient visits for five years and undergo heart tests if required. Healthy participants have no planned follow up.

What are the possible benefits and risks of participating?
Participants may benefit from having their health checked and given health care advice. There are no notable risks with participating.

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

When is the study starting and how long is it expected to run for?
December 2008 to December 2017

Who is funding the study?
Swedish Heart-Lung Foundation (Sweden)

Who is the main contact?
Dr Meriam Åström Aneq

Contact information

Type(s)
Scientific

Contact name
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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
Quantitative CMR analysis of right ventricular function and synchronicity in patients with arrhythmogenic right ventricular cardiomyopathy: Could this be predictive of arrhythmias

Study objectives
The detection of changes in wall deformation and synchronicity in the right ventricle (RV) could indicate a propensity for arrhythmia in arrhythmogenic right ventricular cardiomyopathy ARVC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Linköping, 29/04/2009, ref: M68-09/2009

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Arrhythmogenic right ventricular cardiomyopathy (ARVC)

Interventions
Participants (both healthy controls and those with ARVC) undergo a cardiac magnetic resonance imaging (CMR). This is done for participants as part of their clinical workup for an ARVC diagnosis (according to the international Task Force Criteria). A new acquisition model based on rotated slices has been added to the standard clinical CMR testing and this requires participants to be scanned for an extra ten minutes. The entire CMR investigation takes around 30-40 minutes. CMR images are then evaluated by analysing wall deformation, called “Feature Tracking”.

In addition, participants with ARCV undergo non-invasive testing. This includes an electrocardiogram (ECG), echocardiogram and a 24 hour ECG. These tests are part of the standard clinical evaluation for ARVC patients.

Images from the CMR are analysed and compared to the control group to see how well the CMR is at differentiating between healthy patients and those with ARVC.

No further follow-up is planned for the healthy control group.

Participants with ARVC are followed up with yearly outpatient visits for symptoms of arrhythmia. Holter monitors and echocardiograms are ordered every 2-3 years (or according to the need). In the case that the patient has an ICD implant, the arrhythmia event recorded is evaluated after any clinical events or at the outpatient visits.

Intervention Type
Device

Primary outcome measure
1. Strain values are measured using Feature tracking method once with clinically indicated CMR with additional acquisition model at baseline
2. Time to peak strain is measured using the Feature tracking method with clinically indicated CMR with additional acquisition model at baseline

Secondary outcome measures
Arrhythmia relation to strain values are measuring using the CMR examination with additional acquisition and the yearly interrogation of ICDs and available Holter recordings at year one, two, three, four and five (or when clinically necessary)

Overall study start date
01/12/2008

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Patients:
1. Diagnosis of a definite ARVC
2. Have not received an implantable cardioverter defibrillator (ICD)
3. Aged 18 years and older

Healthy Participants:
1. Age matched asymptomatic who lack a family history of premature cardiovascular disease
2. Not on cardiac medication
3. Pass a cardiac exercise test
4. Aged 18 years and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
All ARVC patients at Linköping University hospital, and without an ICD are included

Key exclusion criteria
The presence of an implantable cardioverter defibrillator (ICD).

Date of first enrolment
30/10/2009

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Sweden

Study participating centre
University Hospital Linköping
Universitetssjukhuset
Linköping
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Sponsor information

Organisation
Linköping University Hospital

Sponsor details
Institute of Medicine and Health Care
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05h1aye87

Funder(s)

Funder type
Charity

Funder Name
Swedish Heart-Lung Foundation (Hjärt-Lungfonden)

Results and Publications

Publication and dissemination plan
Presentation of preliminary study results as a poster abstract was done in 2014 at Euro-CMR. Publication in peer review journal is planned as soon as the manuscript is finalised.

Intention to publish date
15/08/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Meriam Åström Aneq meriam.astrom.aneq@regionostergotland.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/11/2017	18/02/2022	Yes	No