ISRCTN86576368 https://doi.org/10.1186/ISRCTN86576368

Development of a screening tool for cardiac involvement in the Sarcoidosis population using cardiac magnetic resonance imaging (MRI)

Submission date
30/07/2013

Recruitment status
No longer recruiting

Registration date
14/03/2014

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sarcoidosis is a rare condition that causes small patches of red and swollen tissue, called granulomas, to develop in the organs of the body. Although it is more commonly affects organs such as lungs, skin and lymph nodes it can affect any organ in the body, including the heart (cardiac sarcoidosis). Cardiac sarcoidosis is quoted in studies as affecting 25% of patients with sarcoidosis, the most common presentation being sudden death. Despite this there are no guidelines surrounding its management or any screening process to identify those at high risk. This study aims to screen 100 patients with a new diagnosis of sarcoidosis via ECG (electrocardiogram), echocardiography, 48-hour Holter monitor, and finally the gold standard of cardiac MRI (magnetic resonance imaging) for cardiac involvement.

Who can participate?
Any patient between 18 and 65 years old with no other history of cardiovascular disease and no contraindication to a cardiac MRI.

What does the study involve?
Before the cardiac MRI each patient is placed into one of two groups based on findings from initial investigations: 1. Suspected to have cardiac sarcoid. 2. Not suspected to have cardiac sarcoid. The results are compared to those of the cardiac MRI. Each patient found to have cardiac sarcoid is followed up for 1 year following diagnosis to look at disease progression and hopefully give some insight into management, especially with regards to the controversial topic of the need for an implantable cardioverter-defibrillator (ICD). In doing so the researchers hope to find how common a problem it is, to assess the place of simple screening tools in guiding more detailed and expensive investigations, laying the foundation for a screening process. They also hope to look for any clinical evidence that could be used to help in the decision-making process behind the use of ICDs in this population.

What are the possible benefits and risks of participating?
The benefits include catching a very hard to diagnose complication, thus facilitating its treatment. There are no particular risks but drawbacks include a large amount of time and effort on behalf of each patient.

Where is the study run from?
The study will hopefully be run from the Countess of Chester Hospital depending on the number of new sarcoidosis patients. Patients have their cardiac MRI at the Royal Liverpool University Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2013 to September 2015

Who is funding the study?
Countess of Chester Hospital NHS Foundation Trust (UK)

Who is the main contact?
Dr Mohammed Meah

Contact information

Type(s)
Scientific

Contact name
Prof John Somauroo

Contact details
Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Development of a screening tool for cardiac involvement in the Sarcoidosis population using cardiac magnetic resonance imaging (MRI) as the gold standard: an observational study

Study objectives
Sarcoidosis is a granulomatous disease of unknown aetiology. Although it is more commonly affects organs such as lungs, skin and lymph nodes it can affect any organ in the body. Cardiac sarcoid can occur alone or concurrently with multiple organ involvement. It is difficult to diagnose, as often stays clinically silent, though its presence is more common in the sarcoid population in those with cardiac symptoms. It is thought to affect at least 25% of patients with sarcoidosis.

Simple diagnostic tools are useful in the screening of patients with sarcoidosis for cardiac involvement, and allow for risk stratification with regards to sudden cardiac death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Screening

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
Sarcoidosis

Interventions
Patients will be selected from the known sarcoid population at Chester. Patients will be prospectively recruited following new diagnosis of non-cardiac sarcoidosis. They will be put through a screening process beginning with physical examination, ECG, 48-hour Holter monitoring, echocardiogram with tissue Doppler imaging, exercise tolerance test (to exclude ischaemic/coronary artery disease), and finally cardiac MRI as the gold standard. Those found to

have cardiac sarcoid will be treated as normal. They will be followed up for a year (once at 30 days, 6 months and 1 year). All the investigations apart from cardiac MRI will be run again at least once more allowing an assessment of disease progression.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Presence of cardiac sarcoid as per cardiac MRI, measured at baseline and 1, 6 and 12 months following baseline investigations

Secondary outcome measures
1. Biomarkers
2. ECG and Echo findings

Measured at baseline and 1, 6 and 12 months following baseline investigations.

Overall study start date
09/09/2013

Completion date
09/09/2015

Eligibility

Key inclusion criteria
1. Patients with known Sarcoidosis
2. Male and female, aged 18-65 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40-50

Key exclusion criteria
1. Contraindication for cardiac MRI
2. Any other cardiovascular disease (an exercise tolerance test will be done on all participants to assess for ischaemic heart disease)

Date of first enrolment
09/09/2013

Date of final enrolment
09/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
Chester
United Kingdom
CH2 1UL

Sponsor information

Organisation
Countess of Chester Hospital (UK)

Sponsor details
Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
England
United Kingdom
CH2 1UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/041hae580

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Countess of Chester Hospital NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration