

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

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|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>30/07/2013   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>14/03/2014 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>15/10/2020       | <b>Condition category</b><br>Haematological Disorders | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

### Protocol serial number

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

**Study type(s)**

Screening

**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(s)**

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

**Key secondary outcome(s)**

1. Biomarkers
2. ECG and Echo findings

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Countess of Chester Hospital NHS Foundation Trust  
Chester

United Kingdom  
CH2 1UL

## Sponsor information

### Organisation

Countess of Chester Hospital (UK)

### 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

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration