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# Spontaneous coronary artery dissection (SCAD) study

**Submission date**
05/06/2019

**Recruitment status**
No longer recruiting

**Registration date**
10/06/2019

**Overall study status**
Completed

**Last Edited**
25/03/2022

**Condition category**
Circulatory System

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

## Plain English summary of protocol

Background and study aims
Spontaneous coronary artery dissection (SCAD) is a rare cause of acute myocardial infarction with an increased incidence in young women, particularly in the period around giving birth. To date research into this condition in the UK and internationally has been very limited. We propose to undertake (i) detailed vascular phenotypingof an anticipated minimum of 280 patients with a history of SCAD (and matched controls) to determine if the coronary abnormality in SCAD is part of a wider arteriopathy and (ii) investigate whether predilection to SCAD is genetically-based.

Who can participate?
Patients with angiographically proven SCAD (confirmed by the study team) and healthy volunteers.

What does the study involve?
The study involves two elements. Firstly, a registry of patients who have had spontaneous coronary artery dissection and agree to provide access to their medical records, complete questionnaires and provided a blood sample for the research study. Secondly, some patients are invited for a clinical visit day when they undergo lots of different tests to try to understand in what ways their arteries are different from healthy people and to collect samples (blood and sometimes a skin biopsy) to advance laboratory research to understand the causes of SCAD.

What are the possible benefits and risks of participating?
The benefits are altruistic in terms of advancing our understanding of SCAD for the benefit of future patients with this condition. The risks relate only to the blood sampling and skin biopsy (in some patients) which can cause some local discomfort or bruising.

Where is the study run from?
Department of Cardiovascular Sciences, Glenfield Hospital, Leicester, UK

When is the study starting and how long is it expected to run for?
August 2013 to March 2024

Who is funding the study?
1. British Heart Foundation
2. NIHR rare diseases translational collaboration
3. Beat SCAD
4. NIHR Leicester biomedical research centre

Who is the main contact?
Dr David Adlam,
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### Study website
https://scad.lcbru.le.ac.uk/

## Contact information

### Type(s)
Scientific

### Contact name
Dr David Adlam

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
141202

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
14/EM/0056

# Study information

### Scientific Title
Epidemiology, management, outcomes and pathophysiology of SCAD

### Acronym
SCAD

### Study objectives
1. SCAD is associated with remote arteriopathies demonstrable by non-invasive imaging (MRA) and measureable abnormalities of vascular elasticity, compliance and reactivity compared to age and sex-matched controls
2. SCAD has an identifiable genetic basis

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 13/03/2014, NRES Committee East Midlands - Nottingham 1 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0115 8839695; NRESCommittee.EastMidlands-Nottingham1@nhs.net), ref: 14/EM/0056

### Study design
Observiational study with phenotyping and biomarker substudies

### Primary study design
Observational

### Secondary study design
Cohort study

### Study setting(s)
Other

### Study type(s)
Other

### 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
Spontaneous coronary artery dissection

### Interventions
The study has two elements.
The first is an observational registry. Consenting patients allow access to their medical information and clinical imaging at the time and following their Spontaneous Coronary Artery Dissection event and complete a detailed set of online questionnaires. They provide a blood sample for biobanking and DNA. Follow-up questionnaires are also provided annually.

The second element is a deep phenotyping study. Selected patients from the registry are invited to attend for a range of phenotyping investigations which may include: magnetic resonance imaging, magnetic resonance angiography, computed tomography coronary angiography, computed tomography angiography, vascular ultrasound, exercise testing, ambulatory ECG monitoring, retinal photography. A clinical assessment blood sample and skin biopsy sample may be taken.

### Intervention Type
Other

### Primary outcome measure
1. Presenting clinical data from index admission with Spontaneous Coronary Artery Dissection, review of patient notes and imaging, at baseline
2. Demographic, medical, obstetric, contraceptive and family history, review of patient notes, online (bespoke) questionnaires, patient interview, at time of registration
3. Coronary angiographic findings, patient imaging data, at baseline
4. MACCE, SCAD recurrence, pregnancy at follow-up, questionnaires clarified by patient interview if required, annually

### Secondary outcome measures
1. CMR assessment of myocardial function and infarct size, either from scans conducted on clinical grounds or research scans arranged as part of the phenotyping study
2. MRA/CTA assessment of remote arteriopathies either from scans conducted on clinical grounds or research scans arranged as part of the phenotyping study
3. USS assessment of arteries including FMD, IMT, luminal dimensions arranged as part of the phenotyping study
4. Cardiopulmonary exercise testing arranged as part of the phenotyping study
5. Ambulatory ECG monitoring conducted either on clinical grounds or arranged as part of the phenotyping study
6. Blood sampling for biomarkers and genetic studies
7. Skin biopsies for fibroblast culture for laboratory assays

### Overall study start date
11/02/2014

### Completion date
31/03/2024

## Eligibility

### Key inclusion criteria
1. Patients with angiographically proven SCAD (confirmed by the study team).
2. Healthy volunteers

### Participant type(s)
Patient

### Age group
Adult

**Sex**
Both

**Target number of participants**
1,000

**Key exclusion criteria**
Iatrogenic, atherosclerotic or traumatic dissections

**Date of first enrolment**
19/08/2013

**Date of final enrolment**
31/03/2024

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Department of Cardiovascular Sciences**
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9DU

# Sponsor information

**Organisation**
University of Leicester

**Sponsor details**
Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom

LE5 4PW
+44 116 258 4077
UOLSPONSOR@leicester.ac.uk

**Sponsor type**
University/education

**Website**
https://www2.le.ac.uk/colleges/medbiopsych/research/researchgovernance

**ROR**
https://ror.org/04h699437

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation

**Alternative Name(s)**
the_bhf, The British Heart Foundation, BHF

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

**Funder Name**
NIHR rare diseases translational collaboration

**Funder Name**
Beat SCAD

**Funder Name**
NIHR Leicester biomedical research centre

# Results and Publications

## Publication and dissemination plan
Study findings will be published in peer reviewed journals.

## Intention to publish date
01/01/2018

## Individual participant data (IPD) sharing plan
Patient level data are not expected to be made publically available because of issues of patients confidentiality in what is an uncommon disease. Summary data will be presented in publically available peer reviewed manuscripts and posted on the study website (https://scad.lcbru.le.ac.uk/)

## IPD sharing plan summary
Stored in repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2019 | 05/06/2019 | Yes | No |
| Results article | results | 08/01/2019 | 05/06/2019 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |