# Spontaneous coronary artery dissection (SCAD) study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
05/06/2019	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/06/2019	Completed	[X] Results		
<b>Last Edited</b> 22/07/2025	<b>Condition category</b> Circulatory System	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 phenotyping 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, da134@le.ac.uk

# **Contact information**

#### Type(s)

Scientific

#### Contact name

Dr David Adlam

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**Integrated Research Application System (IRAS)** 

141202

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

#### Study type(s)

Other

## 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

## Key exclusion criteria

latrogenic, atherosclerotic or traumatic dissections

#### Date of first enrolment

19/08/2013

#### Date of final enrolment

31/03/2024

# Locations

#### Countries of recruitment

**United Kingdom** 

England

Study participating centre
Department of Cardiovascular Sciences

Glenfield Hospital Groby Road Leicester United Kingdom LE3 9DU

# Sponsor information

### Organisation

University of Leicester

#### **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**

#### 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
Other publications	Association between coronary microvascular dysfunction and exercise capacity in dilated cardiomyopathy	01/12 /2024	22/07 /2025	Yes	No
Other publications	Association between subclinical right ventricular alterations and aerobic exercise capacity in type 2 diabetes	01/12 /2024	22/07 /2025	Yes	No
Other publications	Chronic infarct size after spontaneous coronary artery dissection: implications for pathophysiology and clinical management	03/01 /2020	22/07 /2025	Yes	No
Other publications	PHACTR1 modulates vascular compliance but not endothelial function: a translational study	02/06 /2022	22/07 /2025	Yes	No
Other publications	Spontaneous Coronary Artery Dissection: Pitfalls of Angiographic Diagnosis and an Approach to Ambiguous Cases	16/08 /2021	22/07 /2025	Yes	No
Other_publications	Vascular histopathology and connective tissue ultrastructure in spontaneous coronary artery dissection: pathophysiological and clinical implications	28/05 /2021	22/07 /2025	Yes	No

Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025 No	Yes
	Study website	11/11 /2025	11/11 /2025 No	Yes