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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
22/07/2025

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
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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
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England
United Kingdom

LE5 4PW
+44 116 258 4077
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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
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