

Prediction of cardiovascular risk in chronic coronary syndrome using cardiac troponin

Submission date 23/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/08/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

We have recently shown that a blood test called troponin can predict the severity of a type of heart disease called coronary artery disease on a CT scan in patients who have symptoms suggestive of angina. However we think that troponin could also be able to tell us which patients at the highest chance of future heart attacks or dying from cardiovascular disease. Measuring troponin in patients with coronary artery disease could help prioritise tests and intensify medical treatments in patients who will benefit the most.

Who can participate?

Every patient who attends hospital for an angiogram dye test of their heart arteries for investigation of suspected angina at the Royal Infirmary of Edinburgh, Scotland over a 6 year period from 31/July/2015.

What does the study involve?

Troponin will be measured on the same blood samples that are already routinely taken before the procedure. We will test whether troponin levels can predict the severity of heart disease seen on the angiogram and will look to see if troponin can predict risk of heart attacks or death in the future. This study is being funded by a grant from the British Heart Foundation. The lead contact for this study is Professor Nicholas Mills, Consultant Cardiologist and Professor of Cardiology, University of Edinburgh and NHS Lothian (Nick.Mills@ed.ac.uk)

What are the possible benefits and risks of participating?

None.

Where is the study run from?

Royal Infirmary of Edinburgh (UK)

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

July 2015 to July 2021

Who is funding the study?
British Heart Foundation (UK)
Medical Research Council (UK)

Who is the main contact?
Dr Ryan Wereski, ryan.wereski@ed.ac.uk
Prof Nick Mills, Nick.Mills@ed.ac.uk

Contact information

Type(s)

Public

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

DL-21-016

Study information

Scientific Title

Myocardial Injury in patients attending for Coronary Angiography

Acronym

MICA

Study objectives

We hypothesise that in a population of patients attending for elective coronary angiography, that the concentration of high-sensitivity cardiac troponin will:

1. Predict the prevalence and extent of obstructive coronary artery disease;
2. Predict those patients who are at the highest risk of future adverse clinical events including all-cause mortality, cardiovascular death, and myocardial infarction

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/08/2015, East of Scotland Research Ethics Committee (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: 20/ES/0061

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Patients with suspected or known atherosclerotic coronary disease and chronic coronary syndrome attending for elective coronary angiography

Interventions

This is an observational study which aims to evaluate whether concentrations of high-sensitivity troponin I are associated with severity of coronary artery disease and clinical outcomes in patients attending for elective coronary angiography for investigation of suspected chronic coronary syndrome.

All participants referred for elective coronary angiography for investigation of chronic coronary syndrome at the Royal Infirmary of Edinburgh will be enrolled if routine clinical pre-procedure were taken on the day of the procedure. This study makes use of routinely collected electronic healthcare records and requires no direct involvement from participants. High-sensitivity cardiac troponin will be measured prospectively in the background on blood sample excess to clinical requirement. Attending clinicians will be blinded to the result. Participants care will not be directly impacted by participation. All participants will be followed up until 31/07/2021.

Coronary artery disease severity will be determined by the attending interventional cardiologist at the time of angiography and recorded prospectively in a clinical reporting database (TOMCAT, Philips Cardiovascular Information Management System, Netherlands) before data extraction. The maximal stenosis will be used to define the severity of coronary disease in each major epicardial coronary artery.

Obstructive coronary artery disease is defined by convention as a stenosis $\geq 70\%$ in one or more major epicardial coronary artery or a stenosis $\geq 50\%$ in the left main stem.

Coronary artery disease severity will also be also evaluated using the hierarchical Duke Prognostic Index, which categorizes coronary disease according to extent, location, and stenosis severity.

Routine electronic healthcare data and national registries will be used follow-up the study population for clinical outcome events. All deaths and hospital admissions are recorded on the Register of Deaths in Scotland and the Scottish Morbidity Record (SMR), respectively.

Intervention Type

Other

Primary outcome(s)

Non-fatal myocardial infarction or cardiovascular death up to study end date. This is defined using the International Classification of Disease (ICD)-10 codes of I21 or I22 for myocardial infarction and I00 to I99 inclusive for cardiovascular death. Measured using patient records.

Key secondary outcome(s)

All-cause mortality and coronary revascularization, defined as percutaneous coronary intervention or coronary artery bypass surgery and within 30 days. Measured using patient records.

Completion date

31/07/2021

Eligibility

Key inclusion criteria

1. Elective angiography for evaluation of chronic coronary disease
2. Pre-procedure blood samples obtained on the same day as the procedure
3. Permanently resident in Scotland

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

4917

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

31/07/2016

Date of final enrolment

31/07/2021

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Royal Infirmary of Edinburgh at Little France

51 Little France Crescent

Old Dalkeith Road

Edinburgh

Lothian

United Kingdom

EH16 4SA

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
Borders General Hospital
Huntlyburn Terrace
Melrose
United Kingdom
TD6 9BS

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
St John's Hospital
Howden West
Livingston
Lothian
United Kingdom
EH54 6PP

Sponsor information

Organisation

Accord (United Kingdom)

ROR

<https://ror.org/01x6s1m65>

Funder(s)**Funder type**

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

This project was supported by University of Edinburgh/NHS Lothian DataLoch.

Pseudoanonymised data can be accessed by approved researchers, subject to individual project application, and ethical and governance approval. The privacy notice can be found at <https://dataloch.org/privacy-notice>.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/08/2023	01/08/2023	Yes	No
HRA research summary			26/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes