

# Prediction of cardiovascular risk in chronic coronary syndrome using cardiac troponin

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<b>Registration date</b> 30/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/08/2023	<b>Condition category</b> 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

### Contact name

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Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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?
<a href="#">Results article</a>		08/08/2023	01/08/2023	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes