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Prediction of cardiovascular risk in chronic coronary syndrome using cardiac troponin

Submission date	Recruitment status	[_] Prospectively registered
23/11/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/11/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/08/2023	Circulatory System	

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

Study website
https://dataloch.org/insights/projects-delivered/myocardial-injury-elective-coronary-angiography-mica

Contact information

Type(s)
Public

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not applicable - individual patient consent was not required for this study

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 ≥70% in one or more major epicardial coronary artery or a stenosis ≥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 measure
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.

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

Overall study start date
31/07/2015

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

Age group
Adult

Sex
Both

Target number of participants
4200

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
Scotland

United Kingdom

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)

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QMRI
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Sponsor type
University/education

Website
http://accord.scot/research-access/sponsorship

ROR
https://ror.org/01x6s1m65

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
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Initially, study findings will be published in a peer-reviewed medical journal and presented at a scientific conference. In the past we have worked closely with the media team at the British Heart Foundation, as well as the media team at the University of Edinburgh to help publicise research within the Centre for Cardiovascular Sciences, and disseminate important results. We also publish summary results on the University website for interested members of the public to view. The strategy for this project will follow a similar pattern.

Intention to publish date
01/04/2023

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?
HRA research summary			26/07/2023	No	No
Results article		08/08/2023	01/08/2023	Yes	No