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Improving the care of patients with chest pain in the emergency department

Submission date 07/12/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 07/01/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/02/2024	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
We want to improve Manchester's heart disease care (cardiovascular disease). Greater Manchester has one of the worst rates of heart disease for the United Kingdom, with double the national average for preventable heart disease deaths. The early warning signs for heart disease can be detected and treated enabling patients to live longer and healthier lives. This is where we believe the Emergency Department (ED) can improve, we already collect the vast majority of data required to detect these early warning signs. With more than 23.8 million attendances nationally last year, the ED is currently underusing a large amount of patient data of potentially great value to the population. We are exploring the best way to use this long term heart disease prediction; how to communicate it to patients, who prescribes the necessary medication, who issues lifestyle advice, and who follows it up.
The Troponin-only Manchester Acute Coronary Syndromes (T-MACS) decision aid allows clinicians to rapidly "rule out" the diagnosis of a heart attack when patients present to the Emergency Department with chest pain or similar symptoms.
The aim of this study is to collect historical data to improve the T-MACS tool and to interview patients and staff to investigate the best way to use it.

Who can participate?
The historical data collection will involve data of any patient who presented with chest pain to participating hospitals.
The interview part of the study will involve patients who attend the emergency department with chest pain. Clinical staff including: emergency medicine consultants, general practitioners, and nurses.

What does the study involve?
We will use machine learning techniques on the historical data to identify the best way to continually update T-MACS.
We will conduct semi-structured interviews made up of emergency medicine consultants, general practitioners, nurses, and patients. Then building on the knowledge gained from the initial interviews we plan to conduct four further semi-structured interviews of each aforementioned stakeholder group.

What are the possible benefits and risks of participating?
This trial only involves semi-structured interviews, and we do not believe that it will cover any topics likely to cause distress. Participants are offered a voucher to reimburse them for their time.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2019 to April 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Charles Reynard, charlie.reynard@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
244799

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Qualitative Protocol - v4.0 Quantitative Protocol - v5.2, IRAS 244799, IRAS 263325

Study information

Scientific Title
Advanced cardiovascular risk prediction in the acute care setting; a mixed methods study

Study objectives
Qualitative arm:
To identify the opportunities and barriers to intervening and improving patients heart disease risk from the emergency department
Quantitative arm:
1. To personalise and update an acute myocardial infarction diagnostic algorithm
2. To examine the prognostic ability of routinely collected data to predict long term cardiovascular outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/12/2019, Welsh Research Ethics Committee number 7 (c/o Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB, UK; +44 (0)1267 61 1164; Wales.REC7@wales.nhs.uk), ref: 19/WA/0312 (Qualitative arm)
2. Approved 14/02/2020, Welsh Research Ethics Commitee number 7 (c/o Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB, UK; +44 (0)1267 61 1164; Wales.REC7@wales.nhs.uk), ref: 19/WA/0311 (Quantitative arm)
3. Approved 05/02/2020, Confidentiality Advisory Group (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 797 22557; HRA.CAG@nhs.net), ref: 19/CAG/0209

Study design
Mixed methods multicentre retrospective observational cohort study and semi-structured interviews with a co-design methodology

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis and prevention of cardiovascular disease in patients presenting with chest pain to the emergency department

Interventions
Qualitative arm:
The data collected will be used to create a series of prototype care pathways using a co-design methodology.

The quantitative arm involves large prospectively collected databases which will analysed retrospectively. The data will be cross-linked with NHS Digital Hospital Episode Statistics databases.

Quantitative arm:
Data will be extracted from hospital sites and cross linked with national datasets. This dataset will then be analysed to update and personalise the acute myocardial infarction diagnostic algorithm. This dataset will also be used to assess the routinely collected emergency department data as prognostic factors for long term cardiovascular disease outcomes. Enrolled participants will be invited to two interviews each approximately 30 minutes in length. The first interview will explore the solutions and barriers to introducing a long term cardiovascular care pathway into the acute care setting. From this, a series of prototype pathways will be developed and then feedback sought on them in the second interviews.

Intervention Type
Other

Primary outcome(s)
Qualitative arm:
1. Prototype long term cardiovascular risk prediction pathways for the acute care setting, data with be gathered by two waves of semi-structured interviews at baseline and 6 months analysed using thematic analysis

Quantitative arm:
From patient records:
1. Acute Myocardial Infarction, as per ICD10 coded diagnosis at up to 30 days since index event
2. Cardiovascular Event, as per ICD10 coded diagnosis up to 10 years since index event

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/04/2022

Eligibility

Key inclusion criteria
Qualitative arm:
1. Patients who have experienced chest pain, general practitioners, emergency medicine consultants, emergency department nurses

Quantitative arm:
2. This will use historic data of patients with chest pain. It was collected by bespoke clinical data entry systems in real time

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Qualitative arm:
1. The participants can not attend at least one of the semi-structured interviews
2. Not fluent in English language
3. The ambulatory ward patient’s clinical condition has deteriorated or is severe to the extent that participating in the research would (a) interfere in their clinical care, or (b) that participating would be too strenuous. This will be judged by the nursing staff on the ambulatory care unit, and the clinical academics interviewing the patients
4. Unwilling to take part

Quantitative arm:
5. The study uses historic data. The United Kingdom's national opt service, a registry of patients who do not want their data used for research, will be applied to this data

Date of first enrolment
15/09/2020

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Blackburn Hospital
East Lancashire Hospitals NHS Trust
Haslingden Rd
Blackburn
United Kingdom
BB2 3HH

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Royal College of Emergency Medicine

Alternative Name(s)
RCEM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Research and Innovation Division, Manchester University NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	qualitative	08/04/2022	11/04/2022	Yes	No
Protocol article	quantitative	07/10/2021	28/02/2024	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes