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Reducing unnecessary admissions for chest pain with the Manchester Acute Coronary Syndromes (MACS) decision rule

Submission date
12/06/2013

Recruitment status
No longer recruiting

Registration date
12/06/2013

Overall study status
Completed

Last Edited
15/05/2017

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
When people suffer from chest pain we are often worried that the pains may be coming from a heart problem such as a heart attack. It is often difficult to tell quickly if a patient has pain from a heart problem or from something less serious like a muscle strain. Unfortunately, current blood tests do not give accurate results until at least 12 hours after the chest pain started. This often means an anxious wait and a delay before treatment can start. To help with the problem, we have developed the Manchester Acute Coronary Syndromes (MACS) decision rule from research involving over 1,200 patients. This rule uses blood test results and clinical information collected by the doctor. This rule could identify quickly who has had a heart attack. Many people could be safely reassured that they have not had a heart attack and could go home, avoiding unnecessary hospital admission for further tests. The MACS decision rule also helps doctors to make accurate decisions about the most appropriate ward for patients who do need admission. Before using the rule in practice, we must determine whether using it in reality produces measurable benefit. This will require a large study at many centres across the country. Before starting on this, the aim is to run a smaller study that will find out the possibility of conducting such a large study.

Who can participate?
Adult patients who come to the Emergency Department with chest pain that doctors suspect may have been caused by a heart attack.

What does the study involve?
Participants are randomly allocated to either the usual care group or the MACS decision rule group. Those in the usual care group receive the usual care, with no changes. Where permission is granted, additional blood samples are taken from these participants when they arrive at the Emergency Department and 1 hour later. The samples are stored to be tested for markers of heart disease at a later date, to improve the quality of the tests for heart disease. Participants who are allocated to the MACS decision rule group have their care guided by the MACS decision rule. The initial tests may identify that it is safe for these participants to return home without hospital admission. If so, participants and doctors can still jointly decide whether this is the most

appropriate course of action for the individual participant. The MACS decision rule also allocates participants to one of four risk groups, which the doctor can use to decide the best area of the hospital for the participant to be treated in. Participants who are discharged from hospital early because of the decision rule will be given a follow up appointment. This usually takes place on the following day, but can also be arranged for any time within the next 3 days. This allows staff to take an extra blood sample as an extra check that the participants heart has not suffered any damage. To find out about participants experiences of taking part in this study, some participants are invited to give a detailed account of their experiences either during a telephone interview or during a focus group interview with between 4 and 8 other participants. The interviews are recorded to make sure that important details are not missed. It is very important to know whether the people taking part in this study experience any further medical problems soon after discharge. Participants are therefore contacted by telephone, email, letter or even a home visit (whichever is most convenient) after 7 days, 30 days and 6 months. Finally, participants are sent a questionnaire through the post after 30 days, 3 months and 6 months to find out the details of any health problems they may have had and to work out the costs of those problems to the National Health Service (NHS).

What are the possible benefits and risks of participating?
The researchers cannot promise that taking part in this study will bring benefits to individual participants. It is possible that they will be able to return home sooner. If participants are invited and agree to take part in a focus group or a telephone interview to explore their experiences, they are offered a £10 high street voucher as a token of thanks and, if they have to travel to the hospital for this, travel and parking expenses are reimbursed. As the study does not involve changing the drugs that participants are taking, the risks of taking part are minimal. Previous research suggests that the risks of patients being discharged with an undetected heart attack are extremely small. If participants do go home earlier than usual, they are given an early appointment for a further blood test. If they did have a heart attack that had not previously been detected, it will be picked up by this blood test. If a heart attack is detected, participants will still receive all the appropriate treatment. In very rare cases, taking blood can lead to prolonged bleeding, bruising, accidental damage to the blood vessels and/or infections. However, all blood samples will be drawn by experienced staff members who have received appropriate training. The small amount of blood taken will not have any harmful effects for the participants.

Where is the study run from?
The study is sponsored by Central Manchester University Hospitals NHS Foundation Trust (UK) and will take place at Manchester Royal Infirmary and Salford Royal Hospital (UK).

When is study starting and how long is it expected to run for?
August 2013 to February 2014

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

Who is the main contact?
Dr Richard Body
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Contact information

Type(s)

Scientific

Contact name
Dr Richard Body

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14334

Study information

Scientific Title
Reducing unnecessary admissions for chest pain with the Manchester Acute Coronary Syndromes (MACS) decision rule: feasibility study

Acronym
MACS

Study objectives
The aim of this study is to evaluate the feasibility of a multicentre randomised controlled trial to evaluate whether use of the MACS clinical decision rule can safely reduce unnecessary hospital admissions for suspected cardiac chest pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
21/03/2013, ref: 13/NW/0081

Study design
Randomised; Interventional; Design type: Diagnosis, Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular, Injuries and Emergencies; Subtopic: Cardiovascular (all Subtopics), Injuries and Emergencies (all Subtopics); Disease: Injuries and Emergencies, Congenital Heart Disease and Pulmonary Hypertension

Interventions
1. Control Group: Care of the control group will be guided by local Emergency Department guidelines for the management of suspected cardiac chest pain, which are compliant with current national and international guidance.
2. The intervention group: MACS Decision Rule. This group will have their care in the Emergency Department guided by the use of the Manchester Acute Coronary Syndromes (MACS) clinical decision rule, which combines clinical features with levels of two cardiac biomarkers.
Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Successful early discharge, defined as a decision to discharge from the ED within 4 hours of arrival; Timepoint(s): Assessed once (can be assessed from 30 days after randomisation) (Primary clinical outcome).

Secondary outcome measures
1. Acceptability of trial processes to clinicians and patients; Timepoint(s): Within 30 days of randomisation (feasibility outcome)
2. Attrition (including both failure to complete the trial protocol and loss to follow up); Timepoint(s): Assessed once, on study completion (feasibility outcome)
3. Completeness of data collection; Timepoint(s): Assessed once, on study completion (feasibility outcome)
4. Direct healthcare costs; Timepoint(s): 30 days, 3 months, 6 months
5. Health status (EQ-5D); Timepoint(s): 30 days, 3 months, 6 months
6. Length of initial hospital stay; Timepoint(s): Assessed once, on study completion (clinical outcome)
7. Major adverse cardiac events (death, coronary revascularisation, acute myocardial infarction);

Timepoint(s): 30 days, 3 months, 6 months
8. Patient satisfaction; Timepoint(s): 30 days and 6 months
9. Reasons for lack of compliance with the trial protocol; Timepoint(s): Within 30 days of randomisation (feasibility outcome)
10. The number of eligible patients; Timepoint(s): Assessed once, upon study completion (feasibility outcome)
11. The proportion of eligible patients randomised; Timepoint(s): Assessed once, on study completion (feasibility outcome)

Overall study start date
01/08/2013

Completion date
01/02/2014

Eligibility

Key inclusion criteria
Consenting patients, over 18 years of age, presenting to the ED with pain, discomfort or pressure in the chest, epigastrium, neck, jaw, or upper limb without an apparent non-cardiac source (compatible with the American Heart Association case definitions), which the treating physician believes warrants investigation for a possible acute coronary syndrome.

Target Gender: Male & Female; Upper Age Limit 150 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
1. Peak symptoms occurred more than 24 hours prior to presentation
2. Another medical condition necessitating hospital admission
3. Definite ST elevation myocardial infarction needing immediate revasularisation
4. No capacity to provide informed consent
5. Inability to communicate in English language if translation services are unavailable
6. Prisoners

Date of first enrolment
01/08/2013

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Royal Infirmary
Manchester
United Kingdom
M13 9WL

Study participating centre
Salford Royal Hospital
United Kingdom
M6 8HD

Sponsor information

Organisation
Central Manchester University Hospitals NHS Trust (CMFT) (UK)

Sponsor details
Emergency Department
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	feasibility results	01/09/2017		Yes	No
Results article	patient experiences results	01/09/2017		Yes	No
HRA research summary			28/06/2023	No	No