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A randomised controlled trial of point-of-care cardiac markers in the emergency department

Submission date 31/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2007	**Overall study status** Completed	
Last Edited 06/01/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.shef.ac.uk/chestpain/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/302/19

Study information

Scientific Title

Acronym
RATPAC (Randomised Assessment of Treatment using Panel Assay of Cardiac markers)

Study objectives
To evaluate the clinical effectiveness and cost-effectiveness of the most promising point-of-care cardiac marker panel currently used in the Emergency Department.

Please note that, as of 11/05/2009, the anticipated end date of this trial has been updated from 31/03/2009 to 30/09/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Leeds East Research Ethics Committee on the 27th March 2007 (ref: 07/Q1206/22).

Study design
A pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information sheet can be found at: http://www.shef.ac.uk/content/1/c6/06/76/17/Patient%20information%20sheet.pdf

Health condition(s) or problem(s) studied
Chest pain due to suspected but not proven AMI

Interventions

This is a pragmatic randomised controlled trial and economic evaluation of a point-of-care cardiac marker panel in the management of patients with suspected, but not proven, Acute Myocardial Infarction (AMI) in six Emergency Departments in the United Kingdom. Emergency Department staff will identify eligible patients, provide trial information and obtain written consent.

Participants will be randomised to receive either:
1. Diagnostic assessment using the point-of-care biochemical marker panel, or
2. Conventional diagnostic assessment without the panel.

The only difference between the two arms of the trial will be that patients in the intervention arm will receive testing with the point-of-care panel. The use of all other tests and treatments, and decision-making in the Emergency Department, will be at the discretion of the attending clinician.

The point-of-care cardiac marker panel will comprise Creatine Kinase - Myocardial Bands (CK-MB) (mass), myoglobin and troponin I, measured at presentation and 90 minutes later, using the Biosite Triage cardiac marker panel. This combination has been widely evaluated in practice. An independent evaluation by the Centre for Evidence-based Purchasing found that the Biosite system was reliable and easy to use, and that the ability of the point-of-care method to detect a positive troponin was similar to that of laboratory methods.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportion of patients successfully discharged home after Emergency Department assessment, defined as discharge with no adverse event (defined in next section) during the following three months.

Secondary outcome measures
1. Health utility measured using the Euro Quality of life (EQ-5D) self-complete questionnaire at one and three months after attendance
2. Satisfaction with care measured at one month after attendance using a modified Group Health Association of America questionnaire that has been used successfully in previous studies of diagnostic strategies for acute chest pain
3. The proportion of patients managed on the coronary care unit, receiving cardiac medications (such as heparin, clopidogrel or glycoprotein IIb/IIIa inhibitors) or receiving cardiac interventions (such as angiography, percutaneous intervention or bypass grafting)
4. Re-attendance at and/or re-admission to hospital over the following three months
5. Adverse events (death, non-fatal AMI, emergency revascularisation or hospitalisation for myocardial ischaemia)
6. The proportion of admitted patients ultimately diagnosed as having AMI by European Society of Cardiology (ESC)/American College of Cardiology (ACC) criteria

Overall study start date
01/04/2007

Completion date
30/09/2009

Eligibility

Key inclusion criteria
People presenting to the Emergency Department with chest pain due to suspected but not proven Acute Myocardial Infarction (AMI) in whom a negative point-of-care marker test could potentially rule out AMI and allow discharge home.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
3130

Key exclusion criteria
1. Patients with diagnostic Electrocardiogram (ECG) changes for AMI or high-risk acute coronary syndrome (more than 1 mm ST deviation or more than 3 mm inverted T waves). These patients are at high risk of adverse outcome and require inpatient care even if marker tests are negative
2. Patients with known coronary heart disease presenting with prolonged (more than one hour) or recurrent episodes of typical cardiac-type pain. These patients have unstable angina and require inpatient care for symptom control even if marker tests are negative
3. Patients with proven or suspected serious non-coronary pathology (e.g. pulmonary embolus) that requires inpatient care even if AMI is ruled out
4. Patients with co-morbidity or social problems that require hospital admission even if AMI can be ruled out
5. Patients with an obvious non-cardiac cause (e.g. pneumothorax or muscular pain), in whom AMI can be excluded as a possible cause without resorting to further diagnostic testing
6. Patients presenting more than 12 hours after their most significant episode of pain, for whom a single troponin measurement would clearly be more appropriate than point-of-care panel testing
7. Previous participants in the RATPAC trial
8. Patients who are unable to understand the trial information due to cognitive impairment
9. Non-English speaking patients for whom translation facilities are not available

Date of first enrolment
01/04/2007

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

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http://www.shef.ac.uk/

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name

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	results	01/02/2011		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	01/05/2013		Yes	No