

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

<b>Submission date</b> 31/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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.

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

Not Specified

### **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**

United Kingdom

England

**Study participating centre**

**Medical Care Research Unit**

Sheffield

United Kingdom

S1 4DA

## Sponsor information

**Organisation**

University of Sheffield (UK)

**ROR**

<https://ror.org/05krs5044>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/02/2011		Yes	No
<a href="#">Results article</a>	results	01/05/2011		Yes	No
<a href="#">Results article</a>	results	01/05/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes