

## The RATPAC Trial

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

#### SUMMARY OF THE PROJECT

This is a pragmatic randomised controlled trial and economic evaluation, led by Sheffield University, to be undertaken in six emergency departments in the United Kingdom.

**Aims:** We plan to evaluate the clinical effectiveness and cost-effectiveness of the most promising point-of-care cardiac marker panel currently used in the emergency department comprising of CK-MB, myoglobin and troponin I.

We will measure, in patients presenting to the emergency department with suspected AMI, the effect of using a point-of-care cardiac marker panel upon:

1. The proportion of patients successfully discharged home after emergency department assessment
2. Health-related quality of life and satisfaction with care
3. The use of coronary care beds and cardiac treatments.
4. Subsequent re-attendance at and/or re-admission to hospital
5. Major adverse events (death, non-fatal AMI, emergency revascularisation or hospitalisation for myocardial ischaemia)
6. Health service costs

We also plan to use trial data and blood samples to:

1. Evaluate clinical prediction rules, such as the TIMI and GRACE scores
2. Evaluate potential new or alternative markers, such as ischaemia modified albumin, brain-type natriuretic peptide, myeloperoxidase and fatty acid binding protein.

Cost and outcome data will be collected using routine data sources and self-complete questionnaires mailed to participants at one and three months from the University.

**Patient selection:** People presenting to the emergency department with chest pain due to suspected AMI in whom a negative point-of-care marker test could potentially rule out AMI and allow discharge home.

We will exclude those with:

- a) Diagnostic ECG changes for AMI or acute coronary syndrome (>1mm ST deviation or >3mm inverted T waves),
- b) Known coronary heart disease presenting with prolonged (>1 hour) or recurrent episodes of typical cardiac-type pain,
- c) Proven or suspected serious non-coronary pathology (e.g. pulmonary embolus),
- d) An obvious non-cardiac cause (e.g. pneumothorax or muscular pain), and
- e) Co-morbidity or social problems that require hospital admission.

**Intervention/Control:** We will randomly allocate patients to receive either: a) Diagnostic assessment using the point-of-care biochemical marker panel, or b) Conventional diagnostic assessment without the 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 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.

We will also store blood samples to test new and alternative markers to explore whether these might be more effective or cost-effective than the CK-MB, myoglobin, troponin I panel.

**Costs and outcomes:** The primary outcome will be the proportion of patients successfully discharged home after emergency department assessment, defined as discharge with no adverse event (as defined below) during the following three months.

Secondary outcomes will include: 1) Health-related quality of life measured at one and three months after attendance; 2) Satisfaction with care; 3) The proportion of patients managed on the coronary care unit and receiving cardiac treatments, such as heparin, clopidogrel or glycoprotein inhibitors; 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).

Health service costs will be measured for three months from initial attendance, including diagnostic tests, emergency department attendances and hospital admissions, outpatient reviews, and cardiac procedures.

**Sample size:** We plan to recruit a total of 3130 patients across six hospitals (i.e. ~520 per hospital, depending upon size) over twelve months of recruitment. This will provide 80% power to detect a 5% improvement (from 50% to 55%) in the proportion of patients successfully discharged.

**Project management and funding:** The Trial is funded by the NHS Health Technology Assessment Programme and is sponsored by the University of Sheffield. Steve Goodacre is the Principal Investigator and Liz Cross is the Trial Manager.

Each participating hospital will be provided with a full-time Band 6 Research Nurse for 18 months to provide education, promote recruitment and support data collection. Data collection and questionnaire mailing will be co-ordinated by the University of Sheffield.

**Further information:** Please contact Steve Goodacre ([s.goodacre@sheffield.ac.uk](mailto:s.goodacre@sheffield.ac.uk), 0114 222 0842) or Liz Cross ([e.a.cross@sheffield.ac.uk](mailto:e.a.cross@sheffield.ac.uk), 0114 222 0762)