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The cost-effectiveness of functional cardiac testing in the diagnosis and management of coronary heart disease.

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 12/02/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 99/26/04

Study information

Scientific Title

Study objectives
The aim of this study is to decide whether assessment of myocardial perfusion (by TcMIBI or perfusion MRI or stress echocardiography) in comparison to routine investigation (exercise testing and angiography) can improve the identification of patients who will benefit from revascularisation. The cost effectiveness of each regime will be analysed with respect to more precise targeting of appropriate patients and will include analysis of any implications of change in practice. This study is comparing the clinical and cost effectiveness of cardiac perfusion tests (stress echocardiography, stress MRI, stress MIBI) with the current gold standard test (angiography) for identifying those patients who will benefit from revascularisation (angioplasty or coronary bypass surgery). Patients with unstable angina are randomised to one of the four investigations and assessed at defined time points after treatment. The hypothesis behind this trial is that techniques which measure blood flow to the heart may be more effective than angiography at identifying those patients who are likely to benefit from revascularisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Heart disease

Interventions

Group 1 (control) will have angiography
Group 2 Tc-methoxyisobutylisonitrile (TcMIBI)
Group 3 Magnetic Resonance Imaging (MRI)
Group 4 will have stress echo. The referring cardiologist will have the option of proceeding to angiography but will be urged to do so only when the stress imaging test is 'positive' for reversible ischaemia.
In order to assess clinical confidence in the additional investigations, the cardiologist will record their expected diagnosis and treatment strategy at baseline assessment.
Patients will then proceed to appropriate treatment: Percutaneous Transluminal Coronary Angioplasty
(PTCA) or Coronary Artery Bypass Graft (CABG) or medical therapy.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure is exercise capacity: treadmill time according to modified Bruce protocol measured at baseline, at 6 months following treatment with CABG, PTCA or medical therapy and at 18 months following entry to the trial.

Secondary outcome measures
Secondary measures include the Canadian Cardiovascular Society classification of angina; health related quality of life assessments: the generic SF36, disease specific Seattle Angina Questionnaire and utility EQ-5D; cardiologist's assessment of IHD risk (compared with formal risk assessment) and treatment intentions expressed prior to the diagnostic test; patients' preferences; revascularisation rate; hospital admissions for unstable angina, incidence of MI and deaths after treatment. These outcome measures will be used to evaluate the contribution of functional data to successful revascularisation. Annuitized capital costs will be calculated for each of the imaging procedures. These will be combined with running, treatment, community and patient costs in an incremental cost-effectiveness analysis.

Overall study start date
01/07/2001

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Patients with chronic stable angina and a positive stress exercise test who are referred to designated Papworth cardiologists for angiography will be randomised to one of 4 groups.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
898

Key exclusion criteria
Patients with recent (<3 months) MI, previous or urgent need for revascularisation, those known to have adverse reactions to pharmacological stress, incapable of performing ETT, pacemaker or other contraindication to MRI, not available by telephone.

Date of first enrolment
01/07/2001

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Cardiology
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	01/12/2007		Yes	No
Results article	results	07/02/2014		Yes	No