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Heart Revascularisation Trial - UK

Submission date	Recruitment status	[_] Prospectively registered
30/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/06/2019	Circulatory System	

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
2995

Study information

Scientific Title
Heart Revascularisation Trial - UK

Acronym
Heart Revascularisation Trial - UK

Study objectives
Patients with heart failure, left ventricular systolic dysfunction and definite coronary disease in whom angina is not the predominant symptom will be identified. Cardiac nuclear techniques or stress echocardiography will then be used to identify patients with substantial stress-induced ischaemia or myocardial hibernation/stunning. Patients with either of these problems will be randomised to best medical treatment alone versus best medical therapy and angiography with the intention of, where possible, revascularisation. Revascularisation may be by whichever conventional means the attending cardiologist and cardiac surgeon agree is advisable. Patients will be followed until 90% of patients in the worst performing group have died to determine the effect of the above interventions on all-cause mortality, symptoms, quality of life and recurrent hospitalisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC, ref: 0/3/35

Primary study design
Interventional

Study design
Multicentre randomised interventional process of care and treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
1. Optimal medication plus angiography with, if appropriate, CABG
2. Optimal medication

Follow-up length: 60 months
Study entry: single randomisation only

Intervention Type
Mixed

Primary outcome(s)
Survival

Key secondary outcome(s)
Determine whether coronary revascularisation reduces all-cause and cause-specific hospitalisation

Completion date
20/11/2006

Eligibility

Key inclusion criteria
1. Heart failure (in the investigators opinion) requiring chronic diuretic therapy
2. Coronary disease as the cause of heart failure as evidenced by a history of previous myocardial infarction, previous revascularisation or previous angiography
3. Left ventricular systolic dysfunction (ejection fraction less than 35%)
4. Stress-induced myocardial ischaemia or evidence of myocardial hibernation/stunning affecting five or more left ventricular segments in a 16-segment model
5. Male and female, lower age limit of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
138

Key exclusion criteria
1. Inability to give written informed consent. No age limits are stipulated but patients will have to be over 18 years to give consent and some patients may be considered too frail to survive surgery and would be excluded.
2. Patients who are not candidates for coronary artery bypass graft (CABG) surgery because of frailty or serious co-morbidity, e.g., severe lung disease, metastatic carcinoma. N.B. Some patients will be candidates for percutaneous transluminal coronary angioplasty (PTCA) but prior to randomisation (i.e. prior to doing an angiogram for study purposes) the investigator should be willing to send the patient to CABG surgery in case that is the preferred mode of revascularisation.
3. Unstable angina, myocardial infarction or stroke within the preceding 2 months
4. Patients being considered for revascularisation for the relief of chest pain (angina) or for valve surgery

Date of first enrolment
07/03/2003

Date of final enrolment
20/11/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull and East Yorkshire Hospitals NHS Trust
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Results article	results	01/02/2011	13/06/2019	Yes	No