

Heart Revascularisation Trial - UK

Submission date 30/07/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/07/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/06/2019	Condition category Circulatory System	☐ 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
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

Study design

Multicentre randomised interventional process of care and treatment trial

Primary study design

Interventional

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