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Heart failure revascularisation

Submission date 18/10/2000	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/10/2000	**Overall study status** Completed	
Last Edited 16/05/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Professor John GF Cleland

Contact details
Academic Unit of Cardiology
University of Hull
Castle Hill Hospital
Cottingham
Kingston-upon-Hull
United Kingdom
HU16 5TX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9900791

Study information

Scientific Title

Study objectives
To determine whether coronary revascularisation, improves the survival of patients with heart failure due to coronary disease who have evidence of dysfunctional but viable myocardium or stress-induced ischaemia (but who do not require revascularisation for the relief of angina) and who are receiving optimal medical treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Heart failure with left ventricular systolic dysfunction

Interventions
Best medical therapy versus best medical therapy and revascularisation

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
All-cause mortality

Secondary outcome measures
1. All-cause mortality or myocardial infarction more than 72 hours from coronary revascularisation
2. All-cause mortality and all-cause hospitalisation

3. All-cause mortality and unplanned cardiovascular hospitalisation
4. Days alive and out of hospital
5. Death, non-fatal myocardial infarction or non-fatal stroke
6. Symptom scores for angina and heart failure
7. Quality of life (using EuroHeart Failure, EQ-5D and Minnesota Living with Heart Failure Questionnaires)
8. Mean cost of Therapy (a health economic outcome)

Overall study start date
01/01/2002

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Heart failure (in the investigators' opinion) with left ventricular systolic dysfunction (ejection fraction less than 35%) 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. Stress-induced myocardial ischaemia or evidence of myocardial hibernation/stunning affecting five or more left ventricular segments in a 16-segment model. The core laboratories will make the decision about whether the test identifies a sufficient volume of affected myocardium

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
800

Key exclusion criteria
1. Patients who are not candidates for Coronary Artery Bypass Graft (CABG) because of frailty or serious co-morbidity (eg:- severe lung disease, metastatic carcinoma)
2. Unstable angina, myocardial infarction or stroke within the preceding two months
3. Inability to give written informed consent
4. Unwilling to consent to being contacted directly by staff at the data centre or unwilling to allow their hospital notes to be copied and sent to the data centre
5. Patients being considered for revascularisation for the relief of chest pain (angina) or valve surgery
6. Patients involved in another randomised controlled trial

Date of first enrolment
01/01/2002

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Cardiology
Kingston-upon-Hull
United Kingdom
HU16 5TX

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Initial funding provided by the Medical Research Council (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?
Protocol article	protocol	01/06/2003		Yes	No
Results article	results	01/02/2011		Yes	No