A multi-centre randomised controlled trial of minimally invasive bypass grafting vs angioplasty with stenting for single vessel disease of the left anterior descending coronary artery

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/04/2003	Completed	[X] Results		
Last Edited 08/11/2022	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers HTA 96/04/06

Study information

Scientific Title

A multi-centre randomised controlled trial of minimally invasive bypass grafting vs angioplasty with stenting for single vessel disease of the left anterior descending coronary artery

Study objectives

Coronary artery bypass grafting and angioplasty =/- stenting are both effective but expensive treatments for coronary heart disease. Cheaper alternative procedures with equal or better effectiveness could achieve substantial savings for the NHS. For patients with single vessel disease, Minimally Invasive Direct Coronary Artery Bypass (MIDCAB) is an alternative procedure to angioplasty, which is the "first-line" procedure for this group of patients. Preliminary findings indicate MIDCAB is more effective and potentially cheaper than angioplasty +/- stenting.

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular diseases: Heart disease

Interventions

- 1. Direct coronary artery bypass
- 2. Angioplasty +/- stenting

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The study will assess clinical (recurrence of symptoms, adverse clinical events), functional (exercise ECG, symptom questionnaire), quality of life outcomes (EuroQol, GHQ, and cardiac-specific questionnaires) and health service use (contacts with primary care teams, diagnostic investigations, readmissions, etc) and associated costs. All study patients will be followed for a minimum of 1 year.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

03/05/1999

Completion date

02/10/2002

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration.

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

03/05/1999

Date of final enrolment

02/10/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Cardiac Surgery
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

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

Not provided at time of registration

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	HTA monograph	01/04/2004		Yes	No