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Do patients undergoing coronary artery bypass grafting benefit from concomitant mitral valve surgery?

Submission date 10/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/06/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/06/2011	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
N/A

Study information

Scientific Title
Moderate functional ischemic mitral regurgitation patients randomised to Coronary Artery Bypass Graft (CABG) versus CABG and down-sized ring annuloplasty

Study objectives
In patients with moderate functional ischemic mitral regurgitation, CABG combined with down-sized mitral ring annuloplasty improves freedom from persistent or recurrent mitral regurgitation compared with CABG alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee of Research Ethics and Development of New Technologies, Montreal Heart Institute, Montreal, Qc, Canada. 2 May 2002, ref: CÉRDNT 01-087

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in we format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Functional ischemic mitral regurgitation

Interventions
1. Intervention group: Coronary artery bypass grafting + down-sized mitral ring annuloplasty
2. Control group: Coronary artery bypass grafting
3. Follow-up: Echocardiography 6 months, 1 year

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Mitral regurgitation severity
2. Left ventricular geometry and function
3. Evaluated 6 and 12 months by echocardiography

Secondary outcome measures
1. Mortality: in hospital and 5 years
2. New York Heart Association (NYHA) class: evaluated at 5 years
3. The following outcomes are measured 12 months postop
3.1. 6-min walk test
3.2. Minnesota questionnaire score
3.3. Brain Natriuretic Peptide (BNP)

Overall study start date
28/06/2002

Completion date
01/07/2011

Eligibility

Key inclusion criteria
Moderate (grade 2+) functional ischemic mitral regurgitation in patients undergoing coronary artery bypass grafing

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
58

Key exclusion criteria
1. Papillary muscle rupture
2. Concomitant aortic valve surgery
3. Life expectancy less than 12 months
4. Creatinine > 200 µmol/l

Date of first enrolment
28/06/2002

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Heart Institute
Montreal
Canada
H1T 1C8

Sponsor information

Organisation
Montreal Heart Institute (Canada)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.icm-mhi.org/en/index.html

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Montreal Heart Institute, Quebec (Canada)

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