

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

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| Submission date 10/03/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 28/06/2011 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 28/06/2011 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

Completion date

01/07/2011

Eligibility

Key inclusion criteria

Moderate (grade 2+) functional ischemic mitral regurgitation in patients undergoing coronary artery bypass grafting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/03vs03g62>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Montreal Heart Institute, Quebec (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration