

Prospective Randomised comparison of Off-pump and on-pump Multivessel coronary artery bypass Surgery: analysis of early graft patency by multi-slice computed tomography

Submission date 03/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/03/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/12/2020	Condition category Circulatory System	<input type="checkbox"/> 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
N/A

Study information

Scientific Title

Prospective Randomised comparison of Off-pump and on-pump Multivessel coronary artery bypass Surgery (PROMISS): analysis of early graft patency by multi-slice computed tomography

Acronym

PROMISS

Study objectives

Coronary artery bypass grafting performed without cardiopulmonary bypass (off-pump coronary artery bypass [OPCAB]) has the same early graft patency as if performed with cardiopulmonary bypass (on-pump coronary artery bypass [ONCAB]) and may have reduced complication rate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Hospital da Cruz Vermelha Ethics Committee on the 4th April 2005.

Study design

Prospective, randomised, controlled, single blinded, single centre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multivessel coronary artery disease

Interventions

Patients undergo coronary artery bypass grafting with internal mammary artery, radial or saphenous vein in the two groups using the same anaesthetic protocol, the same graft anastomotic techniques and the same peri-operative (the only exception is heparin dose) and post operative medical treatment. Coronary artery bypass grafting is performed without cardiopulmonary bypass (off-pump group) or with the use of cardio-pulmonary bypass (on-pump group).

Duration of treatment: two surgical methods are compared in PROMISS so the duration of treatment is that of the surgical procedures (3 - 5 hours). Patients are followed at 1 month (clinical exam) and 6 months (clinical exam, quality of life and stress test).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Graft patency at 4 - 6 weeks evaluated by 16 slice computed tomography.

Key secondary outcome(s))

1. Post-operative adverse events
2. Neurocognitive testing at baseline and 4 - 6 weeks
3. Quality of life at baseline and 6 months
4. Adverse events and stress test at 6 months

Completion date

30/01/2008

Eligibility**Key inclusion criteria**

1. Patients between 30 and 90 years
2. Multivessel disease
3. Indication for primary coronary artery bypass graft (CABG) for at least three distal anastomoses according to consensus given by two independent surgeons

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

150

Key exclusion criteria

1. Patient requiring emergency surgery such as:
 - 1.1. Ventilatory support
 - 1.2. Intravenous inotropic therapy
 - 1.3. Cardiogenic shock
 - 1.4. Catheterism accident
 - 1.5. Q-wave myocardial infarction in evolution
2. Need for associated procedures
3. Renal insufficiency or serum creatinine 1.5 times superior to the upper limit normal values
4. Atrial fibrillation
5. Known allergy to contrast material
6. Dyspnoea at rest or inability to hold breath
7. Women with child bearing potential (for the purpose of this study women which have menopause for less than 12 months will be excluded, with exception for those with surgical menopause)
8. Inability to give informed consent

Date of first enrolment

19/04/2005

Date of final enrolment

30/01/2008

Locations

Countries of recruitment

Portugal

Study participating centre

Hospital da Cruz Vermelha

Lisbon

Portugal

1549-008

Sponsor information

Organisation

Hospital da Cruz Vermelha (Portugal)

ROR

<https://ror.org/0120ae790>

Funder(s)

Funder type

Industry

Funder Name

Hospital da Cruz Vermelha (Portugal)

Funder Name

Merck Sharp & Dohme Lda. (Portugal)

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	01/10/2010	31/12/2020	Yes	No
Protocol article	protocol	17/07/2008	31/12/2020	Yes	No