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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/03/2008	**Overall study status** Completed	
Last Edited 31/12/2020	**Condition category** Circulatory System	

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
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 Vemelha Ethics Committee on the 4th April 2005.

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
19/04/2005

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

Age group
Adult

Sex
Both

Target number of participants
150

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 inform 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)

Sponsor details

Rua Duarte Galvao
Lisbon
Portugal
1549-008

Sponsor type
Hospital/treatment centre

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

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	17/07/2008	31/12/2020	Yes	No
Results article	results	01/10/2010	31/12/2020	Yes	No