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Off-pump vs on-pump surgery in patients with stable coronary artery disease

Submission date	Recruitment status	[_] Prospectively registered
21/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2022	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Whady Hueb

Contact details
Av. Dr. Eneas Carvalho Aguiar 44 AB
Sala 114
Sao Paulo
Brazil
05403000

Additional identifiers

Protocol serial number
1926/01/114

Study information

Scientific Title
A randomised comparative study of patients undergoing myocardial revascularisation with or without cardiopulmonary bypass surgery

Acronym
MASS III

Study objectives
The aim of the MASS III Trial is to compare medical effectiveness, safety, cerebral injury, quality of life, cost-effectiveness of coronary surgery with (on-pump) or without (off-pump) cardiopulmonary bypass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (Comissão de Ética para Análise de Projetos de Pesquisa - CAPPesq) approved on 19/10/2001.

Primary study design
Interventional

Study design
Randomised controlled comparative trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Trial operators were required to perform optimum coronary revascularisation in accordance with the current best practices. The surgery was performed by physicians experienced in both on-pump and off-pump bypass surgery techniques. Surgical access to the heart was through a standard median sternotomy in all cases. All incisions and closure techniques were the same for both groups, limiting variability and maintaining blinding of group assignment for patients, family and cardiologists. A cell saver reservoir (COBE Cardiovascular, Inc., USA) was spun down and returned to all patients when the quantity was sufficient.

Off-pump strategies: Off-pump surgery used the Octopus stabiliser described in detail elsewhere. In brief, the distal ends of the two suction arms of the stabiliser are placed on the beating heart on both sides of the target coronary artery. The proximal parts are fixed to the operating table. Through the application of negative pressure, the target area of the heart is sufficiently immobilised to allow the safe construction of the anastomosis of the graft with the recipient artery.

On-pump technique: Conventional coronary artery surgery with cardiopulmonary bypass was accomplished with every effort to minimize the impact of cardiopulmonary bypass. Patients without diabetes received 1 gram of hydrocortisone sodium succinate (SoluCortef®, Pharmacia & Upjohn Co., USA) intravenously before of anesthesia. This procedure will be made only in the on-pump technique.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The following will be assessed at discharge and 5-year follow-up:
1. Incidence of cardiovascular mortality
2. Cerebrovascular accident
3. Non-fatal myocardial infarction
4. Refractory angina requiring revascularisation

Key secondary outcome(s)
The following were assessed at discharge and at 5-year follow-up:
1. Non-cardiac mortality
2. Presence and severity of angina
3. Quality of life, using the 36-item Short Form health survey (SF-36)
4. Cost-effectiveness

Completion date
31/01/2010

Eligibility

Key inclusion criteria
1. Male or female, age 18 years or older
2. Patients with stable angina pectoris and/or documented ischemia due to multivessel disease and preserved ventricular function
3. Angiographically confirmed multivessel coronary artery disease (CAD) with >=70% lesions in at least two major epicardial vessels and at least two separate coronary artery territories (LAD, LCX and RCA)
4. Patients who are eligible for coronary surgery both with and without cardiopulmonary bypass circuit
5. Willing to comply with all follow-up study visits
6. Signed and received a copy of the informed consent

Note: Non-significant left main stenoses can be included

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Age under 18 years
2. Severe congestive hearth failure, New York Heart Association (NYHA) Class III or IV, or pulmonary edema
3. Prior valve replacement or coronary artery bypass graft (CABG) surgery
4. Prior percutaneous coronary intervention (PCI) with stent implantation within 6 months
5. Prior stroke within 6 months or patients with stroke that occurred more than 6 months ago with significant residual neurological involvement, as reflected in a Rankin score >= 1
6. Need for concomitant major surgery e.g. valve replacement, resection ventricular aneurysm, congenital heart disease vascular surgery of the carotid artery, or thoracic-abdominal aorta
7. Concomitant medical disorders making clinical follow-up at least 5 years unlikely or impossible e.g. neoplastic, hepatic, or other severe disease
8. Q-wave myocardial infarction in the previous 6 weeks
9. Hemorrhagic diathesis or hypercoagulability
10. Thoracic deformations technically precluding surgery without extracorporeal circulation
11. Unable to give informed consent

Date of first enrolment
31/01/2002

Date of final enrolment
31/01/2010

Locations

Countries of recruitment
Brazil

Study participating centre
Av. Dr. Eneas Carvalho Aguiar 44 AB
Sao Paulo
Brazil
05403000

Sponsor information

Organisation
Zerbini Foundation (Fundação Zerbini) (Brazil)

ROR
https://ror.org/003c2h870

Funder(s)

Funder type

Charity

Funder Name
Zerbini Foundation (Fundaciao Zerbini) (Brazil)

Results and Publications

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	results	05/08/2014		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	Long-term analysis	19/12/2022	20/12/2022	Yes	No