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The medicine, angioplasty, or surgery study: a randomized controlled clinical trial of three therapeutic strategies for multi-vessel coronary artery disease

Submission date
06/02/2006

Recruitment status
No longer recruiting

Registration date
27/07/2006

Overall study status
Completed

Last Edited
29/09/2022

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
946/94/056

Study information

Scientific Title

The medicine, angioplasty, or surgery study: a randomized controlled clinical trial of three therapeutic strategies for multi-vessel coronary artery disease

Acronym
MASS II

Study objectives
To evaluate the relative efficacies of the possible therapeutic strategies for patients with multi-vessel Coronary Artery Disease (CAD), stable angina, and preserved ventricular function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB), Brazil, 08/08/1994

Study design
Randomized controlled comparative study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary Artery Disease (CAD)

Interventions
In this trial, all patients were placed on an optimal medical regiment consisting of a stepped-care approach using nitrates, aspirin, beta-blockers, calcium channel blockers, Angiotensin Converting Enzyme (ACE) inhibitors or a combination of these drugs, unless contraindicated. 3-Hydroxy-3-Methyl Glutaryl CoA (HMG-CoA) reductase inhibitors were also prescribed along with a low-fat diet on an individual basis. The medications were provided free by the Heart Institute.

Patients were then randomized into three groups to continue with aggressive medical therapy alone or to undergo PCI or CABG concurrent with the medical treatment.

Trial operators were required to do optimum coronary revascularization in accordance with current best practice. Equivalent revascularization was encouraged but was not mandatory.

For patients assigned to have PCI, the procedure was available within three weeks after the assignment. Devices used for catheter-based therapeutic strategies, including stents, lasers, directional atherectomy and balloon angioplasty, were available to the interventionist. Angioplasty was performed according to a standard protocol. Successful revascularization in the PCI group was defined as a residual stenosis of less than 50% reduction in luminal diameter with Thrombolysis in Myocardial Infarction (TIMI) grade flow three.

Patients assigned to the CABG group underwent the operation within 12 weeks after assignment. Complete revascularization was accomplished if technically feasible with saphenous

vein grafts, internal mammary arteries and other conduits such as radial or gastroepiploic arteries. Standard surgical techniques were used under hypothermic arrest with blood cardioplegia. No off-pump CABG was performed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nitrates, aspirin, beta-blockers, calcium channel blockers, Angiotensin Converting Enzyme (ACE) inhibitors and 3-Hydroxy-3-Methyl Glutaryl CoA (HMG-CoA) reductase inhibitors

Primary outcome(s)
1. Non-fatal myocardial infarction
2. Cardiac death
3. Refractory angina requiring revascularization

Key secondary outcome(s))
1. Quality of life
2. Cost comparison
3. Cerebro-Vascular Accident (CVA)

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Stable angina
2. Preserved left ventricular function
3. Two or three vessel disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
611

Key exclusion criteria

1. Unstable angina or acute myocardial infarction requiring emergency revascularization
2. Ventricular aneurism requiring surgical repair
3. Left ventricular ejection fraction of less than 40%
4. A history of Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Graft (CABG) and single vessel disease
5. A history of congenital heart disease
6. Valvular heart disease or cardiomyopathy
7. Inability to understand or cooperate with the protocol requirements or return for follow-up
8. Left main coronary artery stenosis of 50% or more
9. Suspected or known pregnancy
10. Other coexisting condition that was a contraindication to CABG or PCI

Date of first enrolment
10/06/1994

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Brazil

Study participating centre
44 Dr. Eneas Carvalho Aguiar avenue
Sao Paulo
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05403-000

Sponsor information

Organisation
Zerbini Foundation (Brazil)

ROR
https://ror.org/003c2h870

Funder(s)

Funder type
Charity

Funder Name
Zerbini Foundation (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	09/09/2003		Yes	No
Results article	results	19/05/2004		Yes	No
Results article	results	06/03/2007		Yes	No
Results article	results on the association of chronic kidney dysfunction in patients with multivessel chronic coronary artery disease	01/06/2009		Yes	No
Results article	results on the association of TCF7L2 polymorphism rs7903146 and coronary artery disease severity and mortality	17/11/2009		Yes	No
Results article	results	07/09/2010		Yes	No
Results article	results	14/09/2010		Yes	No
Results article	results	20/01/2011		Yes	No
Results article	results	11/09/2012		Yes	No
Results article	results	01/08/2013		Yes	No
Results article	10-year follow-up results	01/11/2013		Yes	No
Results article	10-year results	01/11/2013		Yes	No
Results article	cost-effectiveness results	03/11/2018		Yes	No
Results article	-year follow-up results	01/08/2020	16/12/2020	Yes	No
Results article		22/09/2022	29/09/2022	Yes	No
Other publications	cost analysis	11/09/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes