

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	☐ Prospectively registered ☐ Protocol
Registration date 27/07/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/09/2022	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Brazil

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