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

Submission date	Recruitment status No longer recruiting	[] Prospect		
06/02/2006		[] Protoco		
Registration date	Overall study status	[] Statistica		
27/07/2006	Completed	[X] Results		
Last Edited 29/09/2022	Condition category Circulatory System	[_] Individua		

- tively registered
- al analysis plan
- al participant data

Plain English summary of protocol

Not provided at time of registration

Study website http://www.incor.usp.br

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 multivessel 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

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

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 measure

- 1. Non-fatal myocardial infarction
- 2. Cardiac death
- 3. Refractory angina requiring revascularization

Secondary outcome measures

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

Overall study start date 10/06/1994

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

Age group Not Specified

Sex

Not Specified

Target number of participants

611

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)

Sponsor details

Fundação Zerbini Clinical Research Office Av. Brig. Faria Lima 1.884 - 2º Andar Sao Paulo Brazil 01451-000

Sponsor type Charity

Website http://www.zerbini.org.br

ROR https://ror.org/003c2h870

Funder(s)

Funder type Charity

Funder Name Zerbini Foundation (Brazil)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

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