ISRCTN77449548 https://doi.org/10.1186/ISRCTN77449548

Evaluation of a randomized comparison between patients with coronary artery disease associated with ischemic cardiomyopathy submitted to medical or surgical treatment: MASS-VI (HF)

Submission date
26/09/2019

Recruitment status
No longer recruiting

Registration date
10/10/2019

Overall study status
Completed

Last Edited
06/11/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Ischemic cardiomyopathy and severe left ventricular dysfunction represent one of the main determinants of poor survival prognosis and premature death when compared to preserved ventricular function. However, the role of myocardial revascularization as a therapeutic alternative is not known to improve the long-term prognosis in this group of patients. It aims investigating whether myocardial revascularization, contributes to the better prognosis of patients when compared to those treated with drugs alone and followed in the long term. Methods. It will include 600 patients with coronary artery disease (CAD) associated with ischemic cardiomyopathy. The surgical or drug therapy option will be randomized and the events considered for analysis will be: all cause death, nonfatal infarction and unstable angina requiring additional revascularization and stroke. The events will be analyzed according to the intent-to-treat principle. Patients with multivessel coronary disease and left ventricular ejection fraction (LVEF) measurements of less than 35% will be included. In addition, myocardial ischemia will be documented by myocardial scintigraphy. Markers of myocardial necrosis will be known on admission and after the procedure. Discussion: The role of myocardial revascularization (CABG) in the treatment of patients with coronary artery disease and heart failure is not clearly established. The surgical option of revascularizing the myocardium is a procedure designed to reduce the load of myocardial hibernation in patients with heart failure caused by coronary artery disease. On the other hand, the assessment of myocardial viability is frequently used to identify patients with left ventricular ischemic dysfunction in which CABG may add survival benefit. However, the effectiveness of this option is uncertain. The great difficulty of establishing the efficacy of surgical intervention is based on the understanding of viability without ischemia. Thus, this study will include only patients with viable and truly ischemic myocardium in order to correct this anomaly.

Background and study aims
Ischemic cardiomyopathy and severe left ventricular dysfunction (diseases of the heart muscle)

are serious and often fatal conditions. However, it is not known if myocardial revascularization (use of high-energy lasers to create holes in the heart between the epicardium [outer layer] and the endocardium [inner layer] to allow blood to flow directly from the left ventricle into the myocardium [middle, muscular layer]) can improve the long-term prognosis in this group of patients. Thus, the aim of this study is to investigate whether myocardial revascularization contributes to better prognosis compared to those treated with medical therapy and followed during a long-term follow-up.

Who can participate?
Patients with coronary artery disease

What does the study involve?
The study will include patients with coronary artery disease associated with ischemic cardiomyopathy. They will be randomised to coronary artery bypass grafting or medical therapy alone

What are the possible benefits and risks of participating?
The benefits are related to hibernating myocardial recovery, which will only be obtained by surgical myocardial revascularization. The risks are the same as those observed in surgery with extracorporeal circulation. We accept that myocardial dysfunction may add inherent risks of intervention. Because of this, rigorous myocardial protection will be applied according to protocols directed to this condition

Where is the study run from?
Instituto do Coracao (InCor), Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, Brazil

When is the study starting and how long is it expected to run for?
September 2019 to August 2024

Who is funding the study?
Fundação Zerbini, Brazil

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
4800/19/019 8614, N° CAAE: 10390919.3.0000.0068

Study information

Scientific Title
Hypotheses, rationale, design and methods for prognostic evaluation of a randomized comparison between patients with coronary artery disease associated with ischemic cardiomyopathy submitted to medical or surgical treatment. MASS-VI (HF).

Acronym
MASS-VI (HF)

Study objectives
Myocardial revascularization contributes to the better prognosis of patients when compared to those treated with drugs alone and followed in the long term

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/06/2019, Comissão de Ética para Análise de Projetos de pesquisa do HCFMUSP (Rua Ovídio Pires de Campos, 225 – 5ª andar – Prédio da Administração, São Paulo, SP, Brazil; +55 11 2661-7585; cappesq.adm@hc.fm.usp.br), ref: 10390919.3.0000.0068

Study design
Randomized controlled comparative study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions
Participants will be randomised to receive either revascularization or medical therapy. In all cases, patients will be treated by optimal medical therapy that will include maximum-tolerated beta-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, aldosterone blockers, vasodilators, diuretics, aspirin, and statins. Patients will be followed by outpatient visits every 6 months. The total duration of treatment will be at least for 5 years after randomisation. The treatment randomisation process will be performed by a random sequence generated by a computer-assisted system.

Surgical Treatment: Patients randomized to surgery should have ventricular dysfunction with ejection fraction ≤ 35%, and be a carrier of lesions in multiple arteries. Surgery should be performed with the support of extracorporeal circulation in all patients. In this procedure the myocardial protection should be made with a standardized cardioplegic solution with a temperature close to 35 ºC. Native vessels may receive venous grafts or arterial anastomoses at the discretion of the surgeon. Chronically occluded arteries may receive associated arterial or venous grafts. Obstructed artery endarterectomy may be the surgeon's option. In addition to surgical intervention, patients will receive full medication for CAD as well as rigorous control of risk factors.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Combined primary endpoints will be considered as those that occurred during the study: death from any cause, nonfatal myocardial infarction, stroke and unstable angina requiring additional intervention. All patients will be followed at outpatient visits every 6 months for 5 years

Key secondary outcome(s))
Secondary endpoints, during the study follow-up, will be the graduation of anginal symptoms and also of heart failure. Cardiac decompensation hospitalization will be considered a secondary event. All patients will be followed at outpatient visits every 6 months for 5 year.

Completion date
19/08/2024

Eligibility

Key inclusion criteria
Coronary artery disease (CAD) associated with documented ischemic cardiomyopathy subject to surgical revascularization

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
1. Unsuitable coronary anatomy for revascularization
2. Prior surgical revascularization
3. Implantable heart devices
4. Terminal chronic kidney disease
5. Refusal to sign consent form

Date of first enrolment
19/09/2019

Date of final enrolment
19/09/2021

Locations

Countries of recruitment
Brazil

Study participating centre
Instituto do Coracao (InCor), Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo
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Sponsor information

Organisation
Fundação Zerbini

ROR
https://ror.org/003c2h870

Organisation
Fundação de Amparo à Pesquisa do Estado de São Paulo

ROR
https://ror.org/02ddkpn78

Funder(s)

Funder type
Charity

Funder Name
Fundação Zerbini

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. All data that will be turned public will be anonymised

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/04/2020	06/11/2025	Yes	No
Other publications	Subanalysis	30/08/2024	06/11/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes