

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/10/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Whady Hueb
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Study website

<http://www.incor.usp.br>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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; cappelq.adm@hc.fm.usp.br), ref: 10390919.3.0000.0068

Study design

Randomized controlled comparative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

http://www.incor.usp.br/news/artigos/2012/MASS_27ANOS.pdf

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 $\leq 35\%$, 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 °C. 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 measure

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

Secondary outcome measures

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.

Overall study start date

18/08/2019

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

Age group

Adult

Sex

Both

Target number of participants

600

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

Av. Dr. Enéas de Carvalho Aguiar, N° 44

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São Paulo

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05403000

Sponsor information

Organisation

Zerbini Foundation (Brazil)

Sponsor details

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Sponsor type

Other

Website

<http://www.zerbini.org.br/v2/>

Organisation

Fundação de Amparo a Pesquisa do Estado de São Paulo (FAPESP)

Sponsor details

R. Pio XI, 1500

Alto da Lapa

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55 1138384000

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Sponsor type

Other

Website

<http://www.fapesp.br>

Organisation

Fundação Zerbini

Sponsor details

Sponsor type

Not defined

Website

<http://www.zerbini.org.br/>

ROR

<https://ror.org/003c2h870>

Funder(s)

Funder type

Charity

Funder Name

Fundação Zerbini

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

19/09/2025

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