

Evaluation of cardiac biomarker elevation after percutaneous coronary intervention or coronary artery bypass graft

Submission date 14/03/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/07/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Patients with blockages of the coronary arteries may develop symptoms related to the altered blood supply to the heart muscle, such as chest pain (angina). Most patients with angina can relieve their symptoms with medication. Others may need surgery such as bypass surgery or angioplasty with stent placement, which improve symptoms but may lead to heart injury. This injury can be assessed by laboratory measurement of substances released from the heart. The two most important substances that are measured routinely after these procedures are troponin and creatine-kinase MB. The release of these substances is quite a common event. Although the release of high levels of these substances may indicate heart injury during the procedure, the normal levels of release are not completely understood. It is not known whether this release indicates heart injury or is just related to the procedure itself. The aim of this study is to investigate the relationship between heart injury and levels of troponin and creatine-kinase MB in patients undergoing heart surgery.

Who can participate?

Patients with coronary artery disease and angina who are undergoing heart surgery

What does the study involve?

Participants are assessed using a cardiac magnetic resonance (CMR) scan to look for areas of heart injury. They then undergo heart surgery. After these procedures, blood samples are collected and levels of troponin and creatine-kinase MB are measured. After the participants recover from the procedure they undergo a second CMR. The findings of the second CMR are compared with the first and the new areas of heart injury are compared with the levels of troponin and creatine-kinase MB.

What are the possible benefits and risks of participating?

This study will improve our understanding of what happens to the heart during these procedures and hopefully will help us to identify heart injury during such procedures.

Where is the study run from?

Heart Institute (InCor) Instituto do Coração – HCFMUSP (Brazil)

When is the study starting and how long is it expected to run for?

March 2012 to March 2017

Who is funding the study?

1. Zerbini Foundation (Brazil)

2. Fundação de Amparo à Pesquisa do Estado de São Paulo (Brazil)

Who is the main contact?

Prof. Whady Hueb

Contact information

Type(s)

Scientific

Contact name

Prof Whady Hueb

Contact details

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05403-000

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Prognostic evaluation of cardiac biomarker elevation after percutaneous and surgical revascularization in the absence of manifested myocardial infarction: a comparative analysis of biomarkers and cardiac magnetic resonance

Study objectives

The release of enzyme markers of myocardial cells allows the diagnosis of acute myocardial infarction (AMI), when the levels of Creatine Kinase-MB (CK-MB) or troponin are elevated up to 3 times above the established standard for percutaneous interventions (PCI) and up to 5 times for surgical revascularization - coronary artery bypass graft (CABG) even in the absence of electrocardiographic changes or clinical symptoms. There is doubt about cut-off levels of these biomarkers that lead to myocardial fibrosis, left ventricular dysfunction, and one that implies a

bad prognosis in a long-term follow-up. The hypothesis is that the releasing of biomarkers does not necessarily lead to myocardial fibrosis or left ventricular dysfunction; and the cut-off levels to define periprocedural AMI would be different from the ones established in current guidelines.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board, 15/12/2011, ref: SDC 3736/11/154

Study design

Single-center prospective non-randomized interventional study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Patients with multivessel coronary artery disease and stable angina with formal indication for revascularization procedures

Interventions

Percutaneous coronary intervention using stents - 5 year follow-up

Coronary artery bypass graft with cardiopulmonary bypass (on-pump) - 5 year follow-up

Coronary artery bypass graft without cardiopulmonary bypass (off-pump) - 5 year follow-up

Intervention Type

Procedure/Surgery

Primary outcome(s)

Overall death in a 5-year follow-up

Key secondary outcome(s)

1. Levels of CK-MB isoenzyme and I-Troponin in association with presence of myocardial fibrosis
2. Left ventricle ejection dysfunction assessed by CMR

Completion date

01/03/2017

Eligibility**Key inclusion criteria**

1. Stable angina
2. Multi-vessel coronary artery disease
3. Preserved left ventricular function
4. Formal indication to revascularization procedures (PCI or CABG)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

155

Key exclusion criteria

1. Recent myocardial infarction (≤ 6 months)
2. Signs of manifest or suspected infections
3. Rheumatologic disease activity
4. Chronic renal failure (creatinine level $> 2.0 \text{ mg/dL}$)
5. Recent (≤ 6 months) pulmonary embolism or venous thromboembolism
6. Does not sign the consent form
7. Contraindication for the use of glycoprotein IIb/IIIa inhibitors
8. Cardiac magnetic resonance (CMR) examination, for example, a person with a pacemaker or severe claustrophobia

Date of first enrolment

25/04/2012

Date of final enrolment

23/07/2014

Locations

Countries of recruitment

Brazil

Study participating centre

Zerbini Foundation [Fundacao Zerbini]

Sao Paulo

Brazil

05403000

Sponsor information

Organisation

Zerbini Foundation [Fundação Zerbini] (Brazil)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Zerbini Foundation (Brazil)

Funder Name

Fundação de Amparo à Pesquisa do Estado de São Paulo

Alternative Name(s)

A Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP), São Paulo Research Foundation, State of São Paulo Research Foundation, Foundation for Research Support of the State of São Paulo, FAPESP

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Brazil

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2016		Yes	No
	results	21/11			

Results article		/2017		Yes	No
Results article	results	29/12 /2017		Yes	No
Results article	results	06/12 /2020	07/12 /2020	Yes	No
Other publications	subanalysis in patients with stable coronary artery disease with and without type 2 diabetes	09/07 /2024	16/07 /2024	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes