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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 14/03/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 08/05/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 16/07/2024 | Circulatory System | |

## 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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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Other

## Participant information sheet
Not available in web format, please contact Prof Whady Hueb (whady.hueb@incor.usp.br) to request a patient information sheet

## 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 measure
Overall death in a 5-year follow-up

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

### Overall study start date
01/03/2012

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
150

### 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 >2.0mg/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)

**Sponsor details**
Avenida Dr Eneas de Carvalho Aguiar 44
AB 114 Cerqueira Cesar
Sao Paulo
Brazil
05403000

**Sponsor type**
Charity

**Website**
http://www.incor.usp.br

**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)
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
Local government

### Location
Brazil

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 article | results | 21/11/2017 | | 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 |