

# Type 2 diabetic patients without coronary artery disease: cardiovascular prognosis

<b>Submission date</b> 06/10/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/07/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Diabetes can lead to atherosclerosis, a disease where obstructive plaques build up inside the arteries. This disease may affect the vessels that supply the heart muscle, called the coronary arteries. Patients with such plaques may or may not have symptoms such as chest pain, which usually occurs during exercise or emotional stress and improves with rest. Although diabetes may lead to coronary obstructive plaques, it is still not completely known why some patients do not have this disease. The aim of this study is therefore to study the changes of the coronary arteries and heart function in patients with type 2 diabetes and no evidence of coronary artery disease.

### Who can participate?

Patients with type 2 diabetes and no evidence of coronary artery disease

### What does the study involve?

Participants are assessed for the development of coronary atherosclerosis using angiograms (a type of X-ray to examine blood vessels) and coronary-artery calcium scans at the start of the study and after 5 years of follow-up. In addition, the incidence of cardiovascular events, such as death, myocardial infarction (heart attack) and revascularization procedures are tracked, along with the functioning of the organs that are affected by diabetes, such as the kidneys. In addition, other heart disease risk factors that may play a role in coronary disease are investigated.

### What are the possible benefits and risks of participating?

With this study, we hope to better understand the factors that may be associated with plaque formation in the coronary arteries of diabetic patients.

### Where is the study run from?

University of São Paulo (Brazil)

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

November 2009 to November 2016

Who is funding the study?  
Zerbini Foundation of the Heart Institute, University of São Paulo (Brazil)

Who is the main contact?  
Prof. Whady Hueb  
mass@incor.usp.br

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Whady Hueb

**Contact details**  
Unidade Projeto MASS  
Heart Institute (InCor) Instituto do Coração - HCFMUSP  
Av. Dr. Enéas de Carvalho Aguiar, Nº 44 - Bloco I - AB sala 114  
Sao Paulo  
Brazil  
05403-000  
+55 (0)11 2661 5032  
mass@incor.usp.br

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Hypotheses, rationale, design, and methods for prognostic evaluation in type 2 diabetic patients with angiographically normal coronary arteries: the MASS IV-DM trial

**Acronym**  
MASS IV DM

**Study objectives**  
The aim of the MASS IV-DM Trial is to compare the clinical data, laboratory profile, and angiographic evolution at baseline with that at 5-year follow-up in patients with type 2 diabetes who have angiographically normal coronary arteries.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Scientific and Ethics Committee of the Heart Institute (InCor), Hospital of the Faculty of Medicine, University of Sao Paulo, 15/06/2009, ref: 946/94/56
2. Institutional Review Board (Comissão de Ética para Análise de Projetos de Pesquisa - CAPPesq), 15/06/2009, ref: 264/94

**Study design**

Observational longitudinal case-control single-centre study

**Primary study design**

Observational

**Secondary study design**

Case-control study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Prognosis of coronary artery disease in type 2 diabetic patients

**Interventions**

This study is an observational case-control study with 5 years follow-up.

Diabetic patients with clinically suspected or electrocardiographically documented myocardial ischaemia will undergo coronary angiography, coronary artery calcium scan, doppler echocardiography, arterial stiffness evaluation, laboratory measurements and genetic analysis.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Incidence of major cardiovascular events (myocardial infarction, death and heart failure).

All primary and secondary outcome measures will be assessed every six months for 5 years.

**Secondary outcome measures**

1. Microalbuminuria and renal function
2. Stroke

All primary and secondary outcome measures will be assessed every six months for 5 years.

**Overall study start date**

03/11/2009

**Completion date**

03/11/2016

## Eligibility

**Key inclusion criteria**

Type 2 diabetic patients (both males and females) with a clinical suspicion of coronary insufficiency and electrocardiographic evidence of myocardial ischaemia who have normal coronary angiographies and ventricular function.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

600

**Key exclusion criteria**

1. Age under 18 years
2. Suspected or planned pregnancy
3. Cardiomyopathy
4. Coronary artery disease
5. Heart failure
6. Diabetic renal dysfunction
7. Neoplasia
8. Unable to give informed consent

**Date of first enrolment**

31/03/2010

**Date of final enrolment**

27/10/2011

## Locations

**Countries of recruitment**

Brazil

**Study participating centre**

**University of São Paulo**

Sao Paulo

Brazil

05403000

## **Sponsor information**

**Organisation**

Zerbini Foundation (Brazil)

**Sponsor details**

Heart Institute

University of São Paulo

Av Dr Eneas de Carvalho Aguiar 44

AB sala 114

Sao Paulo

Brazil

05403000

+55 (0)11 3069 5032

whady.hueb@incor.usp.br

**Sponsor type**

Other

**Website**

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

**ROR**

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

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Zerbini Foundation of the Heart Institute, University of São Paulo (Brazil)

## **Results and Publications**

## Publication and dissemination plan

To be confirmed at a later date

## 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?
<a href="#">Results article</a>	results	21/07/2015		Yes	No