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Type 2 diabetic patients without coronary artery disease: cardiovascular prognosis

Submission date
06/10/2009

Recruitment status
No longer recruiting

Registration date
20/10/2009

Overall study status
Completed

Last Edited
13/07/2016

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

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

Primary study design
Observational

Study design
Observational longitudinal case-control single-centre study

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s)
1. Microalbuminuria and renal function
2. Stroke

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

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

Healthy volunteers allowed

No

Age group
Adult

Sex
All

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. Neoplasy
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)

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

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	21/07/2015		Yes	No