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The effects of chronic kidney disease in ischemic cardiomyopathy

Submission date
31/07/2018

Recruitment status
No longer recruiting

Registration date
22/08/2018

Overall study status
Completed

Last Edited
21/07/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) affects patients of different ages and ethnicities worldwide, and is a risk factor for cardiovascular diseases. Creatinine is a protein found in the blood and is used to measure the efficiency of the kidneys. Mild-to-moderate elevations in creatinine in the serum of the blood are associated with increase rates of death, especially from cardiovascular diseases. However, whether CKD independently increases the risk of cardiovascular disease has not been established, and the relationship between kidney function and ischemic cardiomyopathy (weakened heart muscles, a type of cardiovascular disease) is poorly studied.
The aim of this study was to look at the relationship between CKD and ischemic cardiomyopathy in patients with coronary artery disease (CAD).

Who can participate?
Adults with CAD who have previously been treated with angioplasty, myocardial revascularization and clinical treatment according to cardiac and renal function

What does the study involve?
There is no direct involvement from participants in this study, as the study observes the outpatient follow-up period.

What are the possible benefits and risks of participating?
There are no known benefits or risks to participants taking part in this study as it does not involve direct participation.

Where is the study run from?
Heart Institute of the University of São Paulo, Brazil

When is the study starting and how long is it expected to run for?
September 2010 to November 2018

Who is funding the study?
Zerbini Foundation (Brazil)

Who is the main contact?
Dr Thiago Hueb
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Study website
www.incor.usp.br

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of chronic kidney disease in ischemic cardiomyopathy: Long-term follow-up - REVISION-DM2 Trial

Acronym
REVISION DM2

Study objectives
Several studies suggest that mild-to-moderate elevations in serum creatinine levels are associated with increased rates of death from any cause and from cardiovascular causes, but whether chronic kidney disease independently increases the risk of any type of cardiovascular disease has not been established. In addition, the relationship between renal function and ischemic cardiomyopathy remains poorly studied. We aim to look at the effects of chronic kidney disease in ischemic cardiomyopathy.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Institutional Review Board, 25/05/2011, SDC 3585/11/003

Study design
Observational prospective single-center non-randomized outpatients long term follow-up case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic kidney disease in ischemic cardiomyopathy

Interventions
This study will include 2160 patients with coronary artery disease (CAD) previously treated by surgery, percutaneous revascularization, or medical treatment in an outpatient follow-up for 5 years. The ventricular function and glomerular filtration will be determined during the inclusion of the patient in the study. The calculation of the glomerular filtration will be done by the Cockcroft-Gault method and the ventricular function through the echocardiogram by the Simpson method. The major adverse cardiovascular events analyzed during follow-up will include death from any cause, including nonfatal myocardial infarction, unplanned revascularization, and stroke.

Intervention Type
Mixed

Primary outcome measure
The following are assessed throughout the study, from the date of inclusion to the end of the study:
1. Mortality from any cause
2. Non-fatal myocardial infarction, defined as the following:
2.1. Elevation of specific cardiac enzymes within 14 days of a revascularization procedure
2.2. Presence of new Q waves in at least 2 or more contiguous leads
2.3. CK-MB (creatine kinase-muscle/brain)(or troponin US elevation, 10 times above normal level
3. Unplanned cardiac surgery - the need for unplanned revascularization, after symptoms of angina after coronary surgery with or without cardiopulmonary bypass
4. Stroke, defined as one of the following:

4.1. Patients with a focal neurological deficit of central origin, lasting more than 72 hours
4.2. Focal neurological deficit of central origin, lasting more than 24 hours, with imaging evidence of cerebral infarction or intracerebral haemorrhage
4.3. Non-focal encephalopathy, with imaging evidence of cerebral infarction
4.4. Haemorrhage adequate to account for the clinical state
5. Hospital admissions for cardiac causes, including the following:
5.1. Anginal symptoms
5.2. Heart failure
5.3. Generalized edema
5.4. Cardiac arrhythmia
6. Hospital admissions for renal causes, including the following:
6.1. Loss of urinary volume
6.2. Increase of plasmatic potassium without specific cause
6.3. Generalised edema

Secondary outcome measures
Quality of life, assessed every 6 months for 5 years using a questionnaire evaluating topics including the following:
1. Pain
2. Vitality
3. Emotional aspects
4. Physical aspects

Overall study start date
24/09/2010

Completion date
20/11/2018

Eligibility

Key inclusion criteria
1. Stable angina
2. Multi-vessel coronary artery disease
3. Had an evaluation of left ventricular function
4. Aged 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. In dialysis programs
2. Pacemaker
3. Defibrillators
4. Reduced life expectancy
5. Degenerative diseases

Date of first enrolment
25/05/2011

Date of final enrolment
11/07/2016

Locations

Countries of recruitment
Brazil

Study participating centre
Instituto do Coracao (InCor), Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, SP, BR
Av Dr Eneas Carvalho Aguiar 44
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Study participating centre
Zerbini Foundation
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Sponsor information

Organisation
Zerbini Foundation

Sponsor details
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Sponsor type
Charity

Website
www.zerbini.org.br

ROR
https://ror.org/003c2h870

Funder(s)

Funder type
Not defined

Funder Name
Zerbini Foundation

Results and Publications

Publication and dissemination plan
We intend to submit for publication in BMC Cardiovascular Disorders in 2018

Intention to publish date
15/09/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	29/03/2019	Yes	No