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PREVEC Trial: Prevention of Reperfusion damage associated with percutaneous coronary angioplasty following acute myocardial infarction

Submission date
21/01/2013

Recruitment status
No longer recruiting

Registration date
28/01/2013

Overall study status
Completed

Last Edited
03/06/2014

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute myocardial infarction (AMI) is the leading cause of mortality in Chile and worldwide. It also has negative effects on quality of life in survivors.
Existing treatments have reduced mortality. But they have the side effect of restoring the blood flow to the heart which is called an ischemia-reperfusion event. Ischemia-reperfusion increases heart damage through a process called oxidative stress. Ischemia reperfusion damage may be preventable. The aim of the study is to assess whether increasing the antioxidant defences will decrease heart damage. This will be done by giving antioxidant vitamin C (intravenously) and vitamin E (orally) to acute myocardial infarction patients during the standard procedure for AMI called percutaneous coronary angioplasty.

Who can participate?
Patients of either sex, over 18 years old, with an indication of primary percutaneous coronary angioplasty and experiencing their first acute myocardial infarction (symptoms must have started during the last 12 hours).

What does the study involve?
Patients will be randomly allocated to one of two groups. One group (Vitamin-treatment group) will receive the standard procedure for an acute myocardial infarction plus a high-dose infusion of vitamin C and an oral dose of vitamin E.
The other group (Control Group) will receive the standard procedure for an acute myocardial infarction plus an infusion of a harmless substance (saline solution) instead of vitamin C and a harmless oral dose of vegetal oil.
Patients in both groups will give blood at entry, during the intervention procedure and at discharge. Cardiac magnetic resonance assessment will be performed 6 and 84 days after the procedure.

What are the possible benefits and risks of participating?
For the Vitamin-treatment group, it is possible that the infarct size in the heart is reduced in comparison to the Control group. Benefits for the Control group are a longer follow-up by the medical team. Possible reported side effects in the Vitamin-treatment group are lethargy or fatigue (0.17% of patients) and/or phlebitis (0.05% of patients).

Where is the study run from?
The University of Chile Clinical Hospital, Cardiovascular Department (Chile).

When is the study starting and how long is it expected to run for?
The study will start in February 2013 and will run for 3 years or until the required number of 132 patients have been treated and evaluated.

Who is funding the study?
The Scientific and Technological Development Fund (FONDECYT) - Chilean Government

Who is the main contact?
Dr Ramon Rodrigo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1120594

Study information

Scientific Title

PREVEC Trial: Prevention of Reperfusion damage associated with percutaneous coronary angioplasty following acute myocardial infarction: a randomized double-blind placebo-controlled clinical trial

Acronym
PREVEC

Study objectives
Patients subjected to percutaneous coronary angioplasty to restore the coronary blood flow previously impaired by an acute myocardial infarction, while receiving a short-term infusion of high doses of vitamin C, plus oral doses of the recommended dose of vitamin E, will present a lower infarct size, as well as an attenuation of the functional and biochemical damage occurring during the reperfusion following to the sudden loss of blood supply, as compared with placebo-treated patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committees (University of Chile Clinical Hospital, Faculty of Medicine of the University of Chile and Health Ministry of the Chilean Government), 07/2011, ref: Project number - 06-2011

Study design
Randomized double-blind placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please contact Dr. Ramón Rodrigo [rrodrigo@med.uchile.cl] to request a patient information sheet

Health condition(s) or problem(s) studied
Acute Myocardial Infarction

Interventions
Intervention:
Short term massive infusion of intravenous vitamin C (320 mmol/L)
Oral dose of vitamin E (400 IU/day) throughout the protocol
Oral dose of vitamin C (500 mg/12 hours) following angioplasty, throughout the protocol

Control: Placebo

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Infarct size, assessed by cardiac magnetic resonance (CMR) will be measured twice: 6 and 84 days following coronary angioplasty

Secondary outcome measures
Biomarkers for oxidative stress, antioxidant status, heart damage and inflammation will be measured at baseline, at the onset of reperfusion, 6-8 hours after revascularization and at hospital discharge.

Overall study start date
04/02/2013

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Subjects may be of either sex and must be at least 18 years old
2. Subjects must have indication of primary percutaneous coronary angioplasty (PCA) as follows:
2.1. Angina or equivalent at least 120 min duration
2.2. Electrocardiogram (ECG) with STEMI that concerns more than 2 contiguous leads (>2mm)
3. Presentation within 12 h of symptoms onset
4. First myocardial infarction
5. Subject must be able and willing to sign informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
132

Key exclusion criteria
1. History of renal or hepatic insufficiency
2. History of renal lithiasis (oxalates)
3. History of heart failure (NYHA III, IV)
4. Cardiogenic shock
5. Any serious medical co-morbidity that determine life expectancy < 6 month
6. Current participation in any other clinical investigation
7. Pregnancy
8. Glucose 6-phosphate dehydrogenase deficiency

Date of first enrolment
04/02/2013

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
Chile

Study participating centre
Independencia 1027
Santiago
Chile
8380453

Sponsor information

Organisation
Scientific and Technological Development Fund (FONDECYT Fondo de Desarrollo Científico y Tecnológico) (Chile)

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Sponsor type
Government

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https://ror.org/02ap3w078

Funder(s)

Funder type
Government

Funder Name
Scientific and Technological Development Fund (FONDECYT) (Chile) grant number 1120594.

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 provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/05/2014		Yes	No