

Management of hyperglycaemia and platelet activity in patients with acute coronary syndrome

Submission date 11/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/10/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Acronym

CHIPS

Study objectives

A tight glucose control with intravenous insulin in patients suffering from acute coronary syndrome (ACS) would decrease their platelet reactivity compared to subcutaneous insulin.

On 26/06/2008 the sources of funding field was changed from 'Grant application submitted to the Spanish Foundation for Investigation in Science (FIS). Decision pending as of 11/01/2008' to 'Foundation for Development and Cardiovascular Research (Spain)'.

On 10/08/2009 the following changes were made to the trial record:

1. The target number of participants was changed from 200 to 115.
2. The sources of funding was changed from 'Foundation for Development and Cardiovascular Research (Spain)' to 'Foundation for Cardiovascular Research (Fundación Investigación Cardiovascular [FIC]) (Spain)'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee of the Hospital Clinico San Carlos (Coordinación de ensayos clinicos del Hospital Clinico San Carlos), 07/03/2007, amendments approved 12/12/2007, ref: 07/062

Study design

Open single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

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

Acute coronary syndrome

Interventions

Patients are randomised to one of two protocols of glycaemic control.

Intervention group (therapy A): intensive treatment. The aim was to obtain a glycaemia of 80 to 120 mg/dl (4.44 to 6.66 mmol/l). Infusion of insulin is started and hourly controls of the rate of infusion was carried out according to a chart elaborated by the Diabetes Unit of our centre. After 24 hours of insulin infusion, a nocturnal dose of ultra-slow insulin was calculated, together with fast subcutaneous insulin before meals.

Control group (therapy B): standard treatment. The aim was to obtain a glycaemia of less than 180 mg/dl (9.99 mmol/l). The participants were treated with fast subcutaneous insulin before meals, according to a corrective chart, together with slow insulin twice a day (bid). In patients diagnosed with diabetes, the dose of slow insulin was calculated from their previous treatment or according to the weight (0.1 unit per kilogram every 12 h)

As of 10/08/2009, recruitment has ended for this trial. The last patient was recruited on 29/07/2009.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Insulin

Primary outcome measure

1. Effects of treatment on platelet reactivity. Platelet reactivity at baseline, 24 and 48 hours will be assessed by the following:
 - 1.1. Platelet activation: flow cytometry; analysis of platelet P-selectin and GPIIb/IIIa, basal and activated with ADP (1 and 5 μ M) and thrombin receptor activating peptide (TRAP) (1 and 5 μ M)
 - 1.2. Intracellular expression of vasodilator-stimulated phosphoprotein (VASP)
 - 1.3. Soluble sCD40L
 - 1.4. Platelet aggregation
2. Metabolic study: free fatty acids, leptin, adiponectin, and β OH-butyrate. They will be assessed at baseline, 24 and 48 hours, 3, 6, 9 and 12 months of follow-up
3. Influence of platelet polymorphisms on treatment effects. Genetic polymorphisms will be assessed by polymerase chain reaction (PCR) for P-selectin receptor, platelet ADP receptor and phospholipase A2 receptor (PLA2) receptor of GPIIb/IIIa

Secondary outcome measures

Current secondary outcome measures as of 10/08/2009:

Association between the parameters above and cardiovascular major events during follow-up, between different levels of glycaemia, different evolution of diabetes mellitus (quantified by HbA1c, ages of evolution, type of treatment)

Previous secondary outcome measures:

Clinical outcome: association between the parameters above and cardiovascular major events during follow-up. Cardiovascular major events (death, reinfarction, angina, revascularisation, ictus, cardiogenic shock, pulmonary oedema) during follow-up will be recorded.

Overall study start date

26/03/2007

Completion date

26/03/2009

Eligibility

Key inclusion criteria

Consecutive patients admitted to the Coronary Care Unit with ACS and hyperglycaemia will be enrolled if they meet the following criteria:

1. Chest pain in the 24 hours previous to their inclusion
2. Older than 18 years
3. Written informed consent
4. Participant must have one of the following:
 - 4.1. ST segment elevation of at least 0.1 mV in two or more adjacent leads
 - 4.2. New onset left bundle branch block
 - 4.3. ST segment depression of at least 0.1 mV in two or more adjacent leads
 - 4.4. Markers of myocardial necrosis (cardiac troponin I above normal levels)
5. Participants must have one of the following:
 - 5.1. Known diabetes and glycaemia greater than 120 mg/dl (6.66 mmol/l) on admission
 - 5.2. No diagnosis of diabetes and glycaemia greater than 160 mg/dl (8.88 mmol/l) on admission
 - 5.3. No diagnosis of diabetes and glycaemia between 120 to 160 mg/dl at admission, and greater than 120 mg/dl one hour later

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

115 (added 10/08/2009)

Key exclusion criteria

1. Women of childbearing age
2. Inclusion in another clinical trial
3. Life expectancy of less than 1 year
4. High probability of loss on follow-up
5. Unclear origin of chest pain
6. Patients with scheduled percutaneous coronary interventions with complications during the procedure and are admitted to the Coronary Unit, but without chest pain in the last 24 hours

7. Patients on mechanical ventilation
8. Ethical barriers (e.g., patients who are not fluent in Spanish, relatives of investigators)
9. Glycaemia greater than 400 mg% (22.20 mmol/l) on admission

Date of first enrolment

26/03/2007

Date of final enrolment

26/03/2009

Locations

Countries of recruitment

Spain

Study participating centre

c/o Prof Martin Lagos, sn

Madrid

Spain

28040

Sponsor information

Organisation

Hospital Clínico San Carlos, Instituto Cardiovascular (Spain)

Sponsor details

c/o Prof Martin Lagos, sn

Cardiology Department

Madrid

Spain

28040

Sponsor type

Hospital/treatment centre

Website

<http://www.hcsc.es>

ROR

<https://ror.org/04d0ybj29>

Funder(s)

Funder type

Research organisation

Funder Name

Foundation for Cardiovascular Research (Fundación Investigación Cardiovascular [FIC]) (Spain)

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?
Results article	results	01/05/2011		Yes	No