ISRCTN35708451 https://doi.org/10.1186/ISRCTN35708451

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

Submission date 11/10/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/01/2008	**Overall study status** Completed	
Last Edited 02/10/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Antonio Fernandez-Ortiz

Contact details
c/o Prof Martin Lagos, sn
Hospital Clínico San Carlos
Unidad Coronaria
Madrid
Spain
28040

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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 µM) and thrombin receptor activating peptide (TRAP) (1 and 5 µM)
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 ßOH-butirate. 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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes