ISRCTN08189331 https://doi.org/10.1186/ISRCTN08189331

Metabolic control with Glucose-Insulin-Potassium infusion in acute myocardial infarction

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 17/10/2007	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J Klijn

Contact details
Diagram B.V. Zwolle
Van Nahuysplein 6
Zwolle
Netherlands
8011 NB
+31 (0)38 426 2997
j.klijn@diagram-zwolle.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
GIPS II

Study objectives
Treatment with Glucose-Insulin-Potassium (GIK) infusion during the acute phase of myocardial infarction has been proposed as therapeutic intervention for protection of the ischaemic myocardium.

Current evidence suggests an effect in patients with acute myocardial infarction without signs of heart failure at admission treated with reperfusion therapy (i.e. primary coronary angioplasty). There is also evidence for the treatment with insulin-glucose infusion in combination with strict metabolic control for at least three months thereafter for patients with type two diabetes mellitus (i.e. a history of diabetes mellitus, previously treated with oral hypoglycaemic agents or blood glucose level at admission greater than or equal to 11.1 mmol/l) and acute myocardial infarction.

Recently, it has been shown that obtaining and maintaining normoglycaemia (i.e. plasma-glucose concentrations of 4.4 and 6.1 mmol/l) in patients admitted to a Surgical Intensive Care Unit will lead to a marked reduction in morbidity and mortality.

This study will address what the effects will be of metabolic intervention with or without the infusion of GIK on 30-day and one-year mortality in patients eligible for reperfusion therapy (i.e. primary coronary angioplasty or thrombolysis).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Medisch Ethische Toetsings Commissie) on the 2nd May 2003 (ref: 02.1280).

Study design
Randomised, active controlled, parallel group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute myocardial infarction

Interventions
An infusion of 80 mmol potassium chloride in 500 ml 20% glucose with a rate of 2 ml/kilogram body weight/hour over an 12 hour period in a peripheral venous line. The infusion is started as soon as possible after admission to the hospital after determination of blood-glucose level in combination with reperfusion therapy. A continuous infusion of short-acting insulin (50 units Actrapid HM [Novo Nordisk, Copenhagen, Denmark] in 49.5 ml of 0.9 percent sodium chloride) with the use of a perfusor-pump will also be started.
Blood-glucose levels will be measured hourly. Baseline insulin infusion dose and adjustments of insulin dose will be based on a nomogram to obtain and maintain blood-glucose levels of 6.0 to 10.0 mmol/l.

The insulin infusion will be stopped one hour prior to the discontinuation of the glucose-potassium infusion. After the Glucose-Potassium (GK) infusion is stopped insulin may be continued based on glucose measurements according to conventional care or until the infusion rate is less than 1 IU/hour.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glucose-Insulin-Potassium (GIK) infusion

Primary outcome measure
30-day mortality (death from any cause and cardiovascular death).

Secondary outcome measures
1. One-year mortality
2. Analysis of pre-specified subgroups

Overall study start date
01/05/2003

Completion date
01/03/2006

Eligibility

Key inclusion criteria
1. Acute myocardial infarction diagnosed by:
1.1. Chest pain suggestive for acute myocardial infarction
1.2. Symptom-onset less than six hours after hospital admission
1.3. Electrocardiogram (ECG) with ST-T segment elevation more than 1 mV in two or more leads

2. Patients are eligible for either primary coronary angioplasty or thrombolysis
3. Patient who has given his or her informed consent to take part in the study

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
900

Key exclusion criteria
1. Unwillingness to participate
2. Presence of heart failure (either one of these symptoms):
2.1. Heart rate more than 90 beats/minute
2.2. Systolic blood pressure less than 100 mmHg with anterior myocardial infarction
2.3. Killip class greater than or equal to II (third heart sound, greater than or equal to hand-wide rales)

Date of first enrolment
01/05/2003

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Diagram B.V. Zwolle
Zwolle
Netherlands
8011 NB

Sponsor information

Organisation
Isala Klinieken (The Netherlands)

Sponsor details
Locatie Weezenlanden
Department of Cardiology
Groot Wezenland 20
Zwolle
Netherlands
8011 JW

Sponsor type
Hospital/treatment centre

Website
http://www.isala.nl/Pages/default.aspx

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Charity

Funder Name
Netherlands Heart Foundation (The Netherlands)

Funder Name
Guidant (The Netherlands)

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	18/04/2006	Yes	No