Metabolic control with glucose-insulin-potassium infusion in acute myocardial infarction (GIPS II).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25522

Source
NTR

Brief title
GIPS II

Health condition

Acute myocardial infarction eligible for reperfusion therapy.

Sponsors and support

Primary sponsor: Zwolle, Isala Klinieken, locatie Weezenlanden Dr J.H.E. Dambrink
Groningen, Academisch Ziekenhuis Dr S.A.J. van den Broek
AMC Amsterdam

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endpoints are one-year mortality, and analysis of pre-specified subgroups.

Study description

Background summary

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 2 diabetes mellitus (i.e. a history of diabetes mellitus, previously treated with oral hypoglycaemic agents or bloodglucose level at admission „d 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.

Study objective

The study will address what the effects will be of metabolic intervention with or without the infusion of GIK on 30-day and 1-year mortality in patients eligible for reperfusion therapy (i.e. primary coronary angioplasty or thrombolysis).

Study design

N/A

Intervention

An infusion of 80 mmol potassium chloride in 500 ml 20 percent glucose with a rate of 2 ml/kilogram body weight/hour over an 12 hour period in a peripheral venous line (Appendix 1).
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 (see appendix).
The insulin infusion will be stopped 1 hour prior to the discontinuation of the glucose ¡V 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.

Contacts

Public
Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997
Scientific
Diagram B.V. Zwolle
Dokter Stolteweg 96

J. Klijn
Dokter Stolteweg 96

Zwolle 8025 AZ
The Netherlands
+31 (0)38 4262997

Eligibility criteria

Inclusion criteria

Acute myocardial infarction diagnosed by:

1. Chest pain suggestive for acute myocardial infarction;

2. Symptom-onset < 6 hour after hospital admission;

3. ECG with ST-T segment elevation > 1 mV in 2 or more leads.

Patients are eligible for either primary coronary angioplasty or thrombolysis.

Patient who has given his or her informed consent to take part in the study.

Exclusion criteria

1. Unwillingness to participate;

2. Presence of heart failure (either one of these symptoms):

a. Heart rate, > 90 beats/min;

b. Systolic blood pressure < 100 mmHg with anterior myocardial infarction;

c. Killip „d II (third heart sound, „d hand-wide rales).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2003
Enrollment:	900
Type:	Actual

Ethics review

Positive opinion

Date:	12-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL84
NTR-old	NTR114
Other	:
ISRCTN	ISRCTN08189331

Study results

Summary results

1. BMC Med. 2005 Jun 2;3:9.
2. J Am Coll Cardiol. 2006 Apr 18;47(8):1730-1. Epub 2006 Mar 27.
3. Int J Cardiol. 2007 Oct 31;122(1):52-5. Epub 2007 Jan 16.
