Randomised trial to evaluate the clinical value of intensive glucose monitoring and regulation in Acute Coronary Syndromes

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Evaluate the outcomes of a relatively brief but intensive IV insulin therapy compared to conventional therapy in patients admitted for ACS and observe different biomarker washout patterns these treatment groups.Furthermore we wish to determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON32341

Source
ToetsingOnline

Brief title
BIOMArCS Project II; Glucose regulation

Condition

- Coronary artery disorders

Synonym
Myocardial Infarction in diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: Foreest Instituut;Medisch Centrum Alkmaar

Intervention

Keyword: ACS, biomarkers, hyperglycemia, intensive insulin

Outcome measures

Primary outcome

Extend of myocardial damage expressed by Troponin T level at 72 hours.

Secondary outcome

Left Ventricle Ejection Fraction (LVEF) and infarct size at 6 weeks

Extend of myocardial damage as expressed by area under CKMB curve.

ST segment resolution after 6 hours

Serum NTpro BNP values after 0 & 72 hours and 6 weeks

Mortality and non fatal re-infarction

HbA1C and fasting glucose values at 6 weeks.

Biomarkers of (vascular) inflammation, hypercoagulability or neurohumoral

activation at admission, 24, 48 and 72 hours and 6 weeks after randomization

Study description

Background summary

Approximately 40% of patients admitted with ACS have admission hyperglycemia. It has been shown that this has a deleterious prognostic effect, but it has not prospectively been shown that lowering these values leads to better outcomes. Nor has a it been shown what stratgey will work adequately.
We believe that lowering even slightly raised glycemic values will help to limit myocardial infarct size.

The lack of an univocal treatment strategy was very recently addressed in an AHA scientific statement by Deedwania et al calling for further research in this manner.

See:
Deedwania et al; Hyperglycemia and Acute Coronary Syndrome A Scientific Statement From the American Heart Association Diabetes Committee of the Council on Nutrition, Physical Activity,and Metabolism. Circulation. 2008 Mar 25;117(12):1610-9. Epub 2008 Feb 25.)

Study objective

Evaluate the outcomes of a relatively brief but intensive IV insulin therapy compared to conventional therapy in patients admitted for ACS and observe different biomarker washout patterns these treatment groups.
Furthermore we wish to determine whether certain patient groups may benefit more from intensive treatment.

Study design

Single centre, prospective, randomised clinical trail

Intervention

Intensive (48 hours IV insulin) vs. conventional (current expectative treatment)

Study burden and risks

All study participants will additionaly (to standard care) undergo an oral glucose tolerance test, 6 extra bloodsamples and MIBI spect. As described in question E6 is the main additional risk a minor amount of radiation (ca 6 a 7 mSv)
OGTT and bloodsamples carry no noteworthy risks

The intensive treatment group also receives 48hrs IV insulin. We propose that the risk for hypoglycemia is low compared to our current protocol since glucosevalues will be intensively monitored.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Myocardial infarction and hyperglycemia

Exclusion criteria

1. A history of insulin dependent diabetes mellitus (note that patients with non-insulin dependent diabetes mellitus can be included).
2. Myocardial ischemia precipitated by a condition other than atherosclerotic coronary artery disease (e.g. arrhythmia, severe anemia, hypoxia, thyrotoxicosis, cocaine, severe valvular disease, hypotension).
3. Known severely-impaired left ventricular function (ejection fraction <30%) or end-stage congestive heart failure NYHA-class III or IV at presentation (in order to avoid lost-to-follow-up due to non-acute coronary syndrome events).
4. Severe chronic kidney disease with measured or calculated glomerular filtration rate (Cockgroft-Gault or MDRD4 (Modification of Diet in Renal Disease) formula) of <30 ml/min/1.73m2, or renal dialysis40.
5. Co-existent condition associated with a life-expectancy <1 year.
6. Patient is expected to be transferred to another hospital within 48 hours.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2008
Enrollment:	300
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NovoRapid
Generic name:	Insulin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-06-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	21-11-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	25-11-2008

Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	21-05-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
EudraCT	EUCTR2008-001510-24-NL
CCMO	NL22223.094.08