Randomised trial to evaluate the clinical value of intensive glucose monitoring and regulation in Myocardial Infarction

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We postulate the following hypotheses: 1. In patients presenting with myocardial infarction high serum glucose values at admission has a harmful influence on infarct size and left ventricular function (LVF) 2. Systematic, frequent and...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22714

Bron
NTR

Verkorte titel
BIOMArCS-2; glucose regulation

Aandoening

Myocardial Infarction, Acute Coronary Syndrome, ACS, hyperglycaemia

Myocardinfarct, Acuut Coronair Syndroom, hyperglycaemie

Ondersteuning

Primaire sponsor: Foreest Institute Alkmaar
Overige ondersteuning: Foreest Institute Alkmaar

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Extent of myocardial damage expressed by Troponin T level at 72 hours (48 - 96 hours) after admission. If more than one sample is drawn in this time frame, the sample closest to 72 hours will be used.

Toelichting onderzoek

Achtergrond van het onderzoek

The statistical analysis plan can be seen through this link:

https://biomarcscrf.secure.is.nl/Documents/Statistical%20Analysis%20plan%20BIOMArCS2glucose%20-%20FINAL-%209-7-12.pdf

Doel van het onderzoek

We postulate the following hypotheses:

1. In patients presenting with myocardial infarction high serum glucose values at admission has a harmful influence on infarct size and left ventricular function (LVF)

2. Systematic, frequent and intensive glucose level control, with IV insulin in those with abnormal levels will improve LV hemodynamics in ACS patients. This by preserving myocardial tissue and LV function.

3. The beneficial effects of this strategy are modified by treatment delay (i.e. early treatment results in better outcomes), especially in STE-ACSpatients.

4. Effects of intensive insulin can be found on a cellular level as a more favorable biomarker wash out pattern.

Onderzoeksopzet

6 week follow up

Onderzoeksproduct en/of interventie

Treatment for this study only involves managing glucose levels and will not interfere with other treatment strategies, which will be applied according to international guidelines for myocardial infarction at the discretion of the attending physician.

When admission plasma glucose is ¡Ý7.8 mmol/l patients will be asked to participate in our

study. Plasma glucose levels are automatically assessed by converting whole blood glucose levels obtained by Point-of-Care (P-O-C)Glucometer into plasma levels.

Study therapy should be initiated within 2 hours of presentation.

When the patient agrees to participate he/she will be randomly assigned either to the intensive treatment group or to the regular treatment group.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients to be included must meet the following three criteria:

1. Men or women >18 years of age who are admitted with the clinical diagnosis of a myocardial infarction. The diagnosis should be based on the combination of typical ischemic chest complaints and objective evidence of myocardial ischemia or myocardial necrosis as demonstrated by the electrocardiogram (ECG) or elevated cardiac markers, as follows:

- Typical ischemic chest pain, lasting 10 minutes or more, with the onset of symptoms within the preceding 24 hours, and
either

- ECG changes indicative of myocardial ischemia within 24 hours after the onset of chest pain (ECG showing new persistent or non-persistent ST-segment elevation >1.0 mm in two or more contiguous leads)
or

- Elevated biomarkers of myocardial necrosis within 24 hours after the onset of chest pain (i.e. CK-MB >1 times the upper limit of normal of the laboratory (>16 U/L), or Troponin-I > 0.45 ng/ml).

2. Elevated (>7.8 mmol/L) whole blood glucose at admission in patients without a history of insulin dependent diabetes mellitus. (Patients only on oral anti-diabetic agents (NIDDM) can be included)

3. All patients have to provide written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be excluded from this study for any of the following reasons:

1. Myocardial ischemia precipitated by a condition other than atherosclerotic coronary artery disease (e.g. arrhythmia, severe anemia, hypoxia, thyrotoxicosis, cocaine, severe valvular disease, hypotension).

2. 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).

3. 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 dialysis38.

4. Persistent atrial fibrillation.

5. Co-existent condition associated with a life-expectancy <1 year, or otherwise unlikely to appear at all scheduled follow-up visits.

6. Patient expected to be transferred to another hospital within 48 hours.

7. Insulin Dependent Diabetes Mellitus

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1161

Register	ID
NTR-old	NTR1205
Ander register	Foreest Institute Alkmaar : FI 0610
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

De Mulder et al Intensive management of hyperglycaemia in acute coronary syndromes. Study design and rationale of the BIOMArCS 2 glucose trial.
Diabet Med. 2011 Apr 11. doi: 10.1111/j.1464-5491.2011.03307.x (PMID 21480974)