ISRCTN55085730 https://doi.org/10.1186/ISRCTN55085730

Strict glycaemic control in ST-elevation myocardial infarction patients at the coronary care unit using the Paradigm® Real-Time system

Submission date 21/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2009	**Overall study status** Completed	
Last Edited 07/09/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J DeVries

Contact details
Meibergdreef 9
Amsterdam
Netherlands
1100 DD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Strict glycaemic control in ST-elevation myocardial infarction patients at the coronary care unit using the Paradigm® Real-Time system: a single-centre randomised controlled intervention trial

Study objectives
Using the Paradigm® Real-Time system that comprises a glucose sensor, insulin pump, and an algorithm advising the optimal insulin bolus, is beneficial for maintaining strict glycaemic control, as compared to the current standard practice in ST-elavated myocardial infarction (STEMI) patients who are admitted to the Coronary Care Unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the Academic Medical Centre, Amsterdam approved on the 3rd January 2007 (ref: ABR 15308)

Study design
Single centre randomised controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please email J.Hermanides@amc.uva.nl to request a patient information sheet

Health condition(s) or problem(s) studied
ST-elevated myocardial infarction, hyperglycaemia

Interventions
Intervention group:
Insulin treament with sensor augmented insulin pump. Before the STEMI patients are treated with PTCA, an intravenous starting insulin bolus is injected based on the at-admission glucose, using a standardised algorithm and a Paradigm® Real-Time system (combining sensor and pump) is inserted subcutaneously in the abdominal periumbilical skin. If the patient's glucose value exceeds the upper (6.1 mmol/l) or lower range (4.8 mmol/l) an alarm will go off. Pre-meal insulin bolus advice as recommended by the Paradigm Bolus Wizard will be followed. Basal pump rate will be individually calculated and adjusted using a standardised algorithm. After 48 hours, the Paradigm® Real-Time system will be disconnected.

Control group:
Standard care with blinded continuous glucose monitoring. Before treatment with PTCA, the monitoring part of the Paradigm® Real-Time system (so only the sensor, not the pump) is inserted subcutaneously in the abdominal periumbilical skin of those patients randomised to the control group. In the control group, the Paradigm® Real-Time glucose readings are blinded until after the experiment which helps avoiding confusing interference with standard practice. Responsibility for the standard care will remain with the team of nurses and the consulting internal medicine physician. After 48 hours, the Paradigm® Real-Time sensor will be disconnected.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Areas under the curve (AUCs) and percentage of time spent greater than or equal to 7.7 mmol/l and less than or equal to 3.9 mmol/l per patient as assessed by the Paradigm® Real-Time system in the treatment group compared to the control group.

All endpoints (both primary and secondary) will be measured at 48 and 72 hours after admission.

Secondary outcome measures
1. Mean absolute difference between reference blood glucose and glucose values measured by the Paradigm® Real-Time system
2. Bland Altman analysis of the reference blood glucose and glucose values measured by the Paradigm® Real-Time system
3. ST resolution, difference between intervention and control group
4. Changes in cardiological parameters, differences between intervention and control group

All endpoints (both primary and secondary) will be measured at 48 and 72 hours after admission.

Overall study start date
01/07/2007

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Signed informed consent
2. Admitted to the Critical Care Unit (CCU) after primary percutanerous transluminal coronary angioplasty (PTCA) for acute STEMI
3. Admission glucose concentration greater than or equal to 7.7 mmol/l, either known or not known with previous diabetes mellitus
4. Aged 30 - 80 years, inclusive, either sex

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Known type 1 diabetes mellitus
2. Abdominal abnormalities that might hinder either glucose measurement by the sensor or the continuous subcutaneous insulin infusion
3. Any condition that the local investigator feels would interfere with trial participation or the evaluation of results
4. Simultaneous participation in other studies

Date of first enrolment
01/07/2007

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Meibergdreef 9
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
c/o Dr J DeVries
Meibergdreef 9
Amsterdam

Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (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	01/07/2010		Yes	No