

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

<b>Submission date</b> 21/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/09/2011	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

## 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-elevated 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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

ST-elevated myocardial infarction, hyperglycaemia

### **Interventions**

Intervention group:

Insulin treatment 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(s)**

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.

**Key secondary outcome(s)**

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.

**Completion date**

01/09/2009

**Eligibility****Key inclusion criteria**

1. Signed informed consent
2. Admitted to the Critical Care Unit (CCU) after primary percutaneous 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**ROR**

<https://ror.org/03t4gr691>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Academic Medical Centre (AMC) (Netherlands)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/07/2010		Yes	No