Repeated measurements in patients presenting with ST-segment elevation myocardial infarction of Advanced Glycation Endproducts by skin autofluorescence and serum analysis: a pilot study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON39418

Source
ToetsingOnline

Brief title
STAGE study

Condition

- Myocardial disorders

Synonym
''ST segment elevation myocardial infarction'' and ''heart attack''

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Advanced Glycation Endproducts, - Myocardial Infarction, - Skin Autofluorescence

Outcome measures

Primary outcome

The primary endpoints are serial measurements of a) skin AF by the AGE reader®

and

b) value of AGEs as measured in serum. Furthermore, cardiac enzymes levels will

be assessed repeatedly to determine the area under the curve for estimation of

the infarct size.

Secondary outcome

Secundary study parameters/outcome are not applicable

Study description

Background summary

During the last decades, drastic changes in the management of patients presenting with an acute ST-elevation myocardial infarction (STEMI) have substantially improved prognosis at group level. Still, at an individual patient level, the diagnosis of STEMI has an insecure prognosis. The identification of the patient who is at high risk of (repeat) acute coronary syndrome (ACS), including STEMI, poses a major challenge to the treating cardiologist. The development of methods that results in better risk stratification and, subsequently, treatment that is tailored to the need of the individual patient is therefore warranted. The identification (and implementation) of high-risk biomarkers, such as AGEs, can significantly contribute to this development. High levels of serum Advanced Glycation

Endproducts (AGEs) and skin autofluorescence (AF) measured by the AGE reader® seem to be well correlated with coronary heart disease. The change in AGEs levels as measured in serum and by skin AF during the acute phase and first few days after admission for ST elevation myocardial infarction (STEMI) through repeated measurements has not been investigated. Such serial follow-up might reveal relations between AGEs levels and the clinical course of STEMI patients.

Study objective

The objectives of this study in STEMI patients are as follows:

Primary objectives:
- To investigate the kinetics of AGEs in the acute phase of STEMI by repeated measurements with the AGE reader® through skin AF, as well as by determining serum AGEs through repeated blood sampling
- To investigate whether the development of AGEs during the first days after the infarction is related to myocardial infarct size as measured by the release of cardiac enzymes

Secondary objectives:
- To investigate the relationship between cardiac enzymes and serum AGEs / skin AF
- To correlate serial measurements of skin AF levels with serial serum AGEs levels

Study design

This is a prospective observational pilot study, which will be performed at the department of Cardiology of the Erasmus MC in Rotterdam. The study sample will include 40 STEMI patients, who are admitted to the Cardiac Care Unit (CCU) of the Erasmus MC within 6 hours after symptom onset. As a routine treatment option for patients presenting with the symptoms and signs of STEMI, primary percutaneous coronary intervention (PCI) will be conducted in these subjects. Over four successive days repeated measurements will be implemented with the AGE reader® and (fasting) blood samples will be taken simultaneously. These follow-up measurements might be conducted in the Vlietland Ziekenhuis (Schiedam), the Sint Franciscus Gasthuis (Rotterdam) and the Havenziekenhuis (Rotterdam), depending on the clinical course of the patient. (Note that most STEMI patients that undergo primary PCI in the Erasmus MC will be discharged within 24h to one of the general hospitals in the Rotterdam region)

Study burden and risks

The extra overnight fasting blood samples, that will be drawn on day 2, 3 and 4, form the main burden to the participants of this study. However, by combining the venipunctures for the purpose of this study with the planned

blood sampling as a part of standard medical care, we will minimise this burden. Additionally, the patients will be submitted to repeated measurements of skin AF with the AGE reader®. In our opinion, the risks and burden associated with these procedures are low and counterbalance the scientific benefit of this study.

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

- Men and women, aged from 18 year, capable of understanding the study content of and willing to provide written informed consent at admission to the hospital.
- Diagnosis of STEMI, according to the guidelines of the European Society of Cardiology (ESC) 2008. The diagnosis is defined as a history of chest pain / discomfort lasting for 10 - 20 minutes or more (not responding fully to nitroglycerine) with persistent ST segment

elevation and elevated markers of myocardial necrosis. Other causes of chest pain / discomfort must be ruled out by the cardiologist.
- Symptom duration <6h.

Exclusion criteria

- Admission for an ACS <6 months
- Clinically significant renal disturbance (GFR (MDRD) <= 30 mL/min/1.73m2) or known renal disease
- Severe inflammatory or current malignant disease
- Darkly coloured skin
- Auto-immune / connective tissue disease
- Aorta dissection
- Comatose at admission to the CCU

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2012
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL40381.078.12