

Follow up MISSION!: Optimization of chronic care for patients with acute myocardial infarction and long term course of cholesterol.

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Primary Objective:- To assess lipid levels of STEMI patients over a long course. Secondary Objectives:- To assess the association between poorly controlled cholesterol and (apo) lipoprotein levels for the long term outcome in STEMI patients.- To...

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON43755

Source

ToetsingOnline

Brief title

Long term follow up of STEMI patients: outcome and course of cholesterol.

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Atherosclerosis, stenosis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adherence, Cholesterol, Outcome, STEMI

Outcome measures

Primary outcome

- Association between baseline characteristics, place of referral and poorly controlled lipid levels.

Secondary outcome

- A major coronary event after one year follow up (defined as death from CHD, nonfatal non*procedure-related myocardial infarction, or resuscitation after cardiac arrest), a cerebrovascular event, hospitalization for congestive heart failure, peripheral-artery disease, death from any cause, any cardiovascular event, and any coronary event.

- Statin compliance using the MMAS (Morisky Medical Adherence Scale).

Study description

Background summary

Over seven million people die from CAD every year, accounting for 12.8% of all deaths. In the Leiden University Medical Center patients with a ST-segment elevated myocardial infarction (STEMI) are treated according to the MISSION! Protocol. This protocol was implemented in 2004 and contains a clinical framework designed to optimize the care of STEMI patients. However, treatment of these patients remains suboptimal, in particular regulation of lipids, which is a well-known risk factor for recurrent cardiac events. Analysis shows that 2

years after STEMI, only 9.3% of all patients reach the target level of 1.8mmol/L for low density lipids (LDL) cholesterol. In addition, less than 50% of the patients were statin therapy compliant 1 year after STEMI.

Study objective

Primary Objective:

- To assess lipid levels of STEMI patients over a long course.

Secondary Objectives:

- To assess the association between poorly controlled cholesterol and (apo) lipoprotein levels for the long term outcome in STEMI patients.
- To assess factors associated with poorly controlled lipid levels.
- Assessment of long term statin compliance using the MMAS scale.

Study design

Prospective observational cohort study.

Study burden and risks

Patients will be asked to visit the hospital once or twice for a blood sample and to fill in a questionnaire. The risk of complications with a venipuncture, such as syncope or phlebitis is considered to be low.

The outcome of this study might benefit future lipid regulations and associated outcomes in STEMI patients. This study will provide insight in medication compliance in STEMI patients and whether this is associated with type of health care professional controlling the lipid levels.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- All consecutive patients with ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) treated by the MISSION! Protocol from 01-02-2004 to 31-12-2013.

* STEMI is defined as ongoing chest pain (>30 minutes), accompanied with ST-elevation (*0.2 mV in *2 leads in V1-V3 or *0.1 mV in other leads) or presumed new left bundle branch block (LBBB) and a typical rise and fall of cardiac biomarkers. Patients with a cardiac arrest are only analyzed if there is return of spontaneous circulation at the time of treatment in the catheterization lab.;- Place of residency area Hollands-Midden Noord at the time of index infarction.;- Measured lipid spectrum (Total-cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides) at the time of index infarction.

Exclusion criteria

- Patients with other acute coronary syndromes as non-ST-elevated myocardial infarction or unstable angina pectoris, not treated with primary PCI are excluded. Patients will also be excluded in case of cardiac arrest without return of spontaneous circulation at the time of primary PCI.;- If the permanent residence of the patient is not in the Netherlands, follow-up for clinical outcomes can be difficult. For this reason these patients will be eliminated for clinical outcome analysis.;- Not completed outpatient follow up according to the MISSION! guidelines, up to one year following index infarction.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 25-03-2016

Enrollment: 600

Type: Anticipated

Ethics review

Approved WMO

Date: 18-05-2016

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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

CCMO

ID

NL55078.058.15