Potential overestimation of plasma non-esterified fatty acid levels (NEFA). The effect of in-vitro lipoprotein lipase inhibition with tetrahydrolipstatin on NEFA in heparinized patients undergoing percutaneous coronary interventions.

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To quantify the effect of THL on the laboratory analysis of NEFA in heparinized patients with AMI undergoing primary PCI

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

Summary

ID

NL-OMON31946

Source
ToetsingOnline

Brief title
NEFA concentrations during primary PCI for acute myocardial infarction.

Condition

- Coronary artery disorders

Synonym
coronary artery disease; increased lipid levels

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: 1. Society of Cardiac Anesthesia. 2. Restant van Nederlandse Hartstichting subsidie.

Intervention

Keyword: Heparin, NEFA, Primary PCI, Tetrahydrolipstatin

Outcome measures

Primary outcome

The degree of difference between NEFA levels analyzed in the absence and

presence of THL in the test tube during blood sampling

Secondary outcome

LPL

APTT

Study description

Background summary

Dramatic increases in plasma non-esterified fatty acid levels (NEFA) heve been reported in patients with acute myocardial infarction (AMI). This appears to be especially so when heparin is used, as in acute percutaneous coronary interventions (PCI). It has been suggested that very high NEFA levels are associated with inhibition of myocardial metabolic and mechanical function, especially following ischemia and reperfusion.
However, it has been demonstrated in healthy volenteers and in patients undergoing cardiac surgery that NEFA levels may be substantially overestemated (> 50%). This is probably caused by the occurrence of ongoing lipolysis in the test-tube (ex-vivo) due to the presence of high levels of lipoprotein lipase (LPL). Plasma levels of LPL are increased following intravenous administration of heparin. To prevent the ongoing lipolysis in the test tube, a blocker of LPL activity has been used. This is tetrahydrolipstatin (THL). To date, the use of such an LPL blocker in cardiac patients has not been described.
Therefore, we postulate that dramatic elevation of NEFA at early reperfusion during PCI (to values >> 1 mMol/L), is caused by overestimation. To test our

hypothesis, the present study is designed to quantify the impact of THL on the laboratory analysis of NEFA in non-diabetic and diabetic patients with ST segment elevation myocardial infarction (STEMI), undergoing acute percutaneous coronary interventions (PCI).

Study objective

To quantify the effect of THL on the laboratory analysis of NEFA in heparinized patients with AMI undergoing primary PCI

Study design

Prospective, non-randomized comparison of two laboratory techniques.

Study burden and risks

1. Three EXTRA venapunctures may be painful and may lead to hematoma.
2. 100 ml of EXTRA blood sampling for the study only (over a period of 28h) may lead to some drop in hemoglobin levels.

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

Non-diabetic and diabetic patients with acute myocardial infarction undergoing primary percutaneous coronary angioplasty

Exclusion criteria

Participation in another clinical research study within 30 days of enrollment.
Hemoglobine level < 7 mmol/l prior to start of PCI procedure.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL21688.018.08