PCI vs thrombolysis in acute myocardial infarction: a prospective study on the effects of cardiac and psychological risk factors on prognosis and quality of life SUBSTUDY: Endothelial dysfunction in ACS patients with and without depression

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the proposed study will examine the differences in flow-mediated vasodilatation of the brachial artery in depressed and non-depressed post-MI patients.

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

Summary

ID

NL-OMON30999

Source
ToetsingOnline

Brief title
Endothelial dysfunction in ACS patients with and without depression

Condition

- Coronary artery disorders
- Mood disorders and disturbances NEC

Synonym
depression, endothelial dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, Endotheel dysfunctie, myocardial infarction

Outcome measures

Primary outcome

Examine the predictive effects of depressive symptomatology on arterial

endothelial function in post-MI patients

Secondary outcome

nvt

Study description

Background summary

It is evident from previous studies that post-MI depression negatively affects prognosis. However, the mechanisms by which depression exerts this negative effect are still largely unclear, although there several candidate mechanisms have been identified. One potential mechanism could be arterial endothelial dysfunction, since this is a characteristic present in both cardiac patients and depressed psychiatric patients.

Study objective

the proposed study will examine the differences in flow-mediated vasodilatation of the brachial artery in depressed and non-depressed post-MI patients.

Study design

This is a single-center observational study, embedded in a large longitudinal

multi-center study examining the effects of post-MI depression on prognosis.

Study burden and risks

There may be some, relatively small, discomfort associated with the administration of nitroglycerin, since the vasodilatation it causes, may also cause headache. Otherwise, there is minimal risk and therefore minimal burden associated with this study. We chose post-MI patients specifically because we aim to examine potential mechanisms of disease in subgroups (depressed vs. non-depressed) of this patient group.

Contacts

Public
Universiteit van Tilburg

Warandelaan 2
5000 LE Tilburg
Nederland
Scientific
Universiteit van Tilburg

Warandelaan 2
5000 LE Tilburg
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Documented CHD (by previous myocardial infarction) and participation in previously started prospective multi-center study (METC number: M03/1302).

Exclusion criteria

cardiomyopathy, valvular heart disease, congestive heart failure, left bundle branch block, Wolff-Parkinson-White syndrome, resting blood pressure > 200/120 mmHg, ejection fraction <35%, left main coronary artery stenosis >49%, clinically significant bradycardia and hypotension (for the nitroglycerin part of the test only).

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):	01-10-2008
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL19466.060.07