Left Ventricular Thrombus Formation after Acute Myocardial Infarction - a randomized multi-center trial comparing 2 different anti-thrombotic regimens

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The objective of this study is to determine in a randomized fashion the risks as well as the benefits of the addition of vitamin K antagonists to dual anti-platelet therapy in patients with PCI-treated STEMI and LV thrombus formation

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON43624

Source
ToetsingOnline

Brief title
LV thrombus after AMI

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
LV thrombus formation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: zonMW,Hartstichting

Intervention

Keyword: LV thrombus, magnetic resonance imaging, myocardial infarction, therapy

Outcome measures

Primary outcome

Primary outcome is defined as the proportions of patients with new cerebral micro-infarcts at 6 months relative to baseline measured by MRI.

Secondary outcome

The secondary endpoints as assessed at 6 and 12 months are:

• the composite of vascular death, recurrent myocardial infarction, stroke or systemic embolism

• presence of new cerebral mirco-bleeds

• the occurrence of major and minor bleeding

• neurological status and quality of life.

Study description

Background summary

Left Ventricular (LV) thrombus formation is witnessed in at least 10% of patients with ST elevation myocardial infarction (STEMI). It is a feared complication since it might increase the risk of thrombo-embolic events, including fatal stroke. Guidelines recommend vitamin K antagonist treatment in these patients. However patients with STEMI nowadays undergo primary percutaneous coronary intervention (PCI) with coronary stent placement and consequently require dual anti-platelet therapy (ascal and clopidogrel) to prevent stent thrombosis. Consequently, STEMI patients with LV thrombus are currently treated with triple antithrombotic therapy (aspirin, thienopyridine class antiplatelet agent, e.g. clopidogrel (75 mg/d) and vitamin K antagonist). Patients treated with triple antithrombotic therapy are subject to a strongly increased bleeding risk with a yearly incidence of 3.7% for dual anti-platelet

therapy as compared to 12% for triple antithrombotic therapy. About 10% of these bleedings are cerebral. The mortality of such haemorrhagic strokes is 25%. A recent retrospective analysis did not show any beneficial effects of addition of vitamin K antagonist to dual anti-platelet therapy to prevent stroke. If vitamin K antagonist-therapy could be omitted, morbidity and mortality due to post-PCI bleedings will decrease. Therefore, a randomized trial is warranted to address this issue.

Study objective

The objective of this study is to determine in a randomized fashion the risks as well as the benefits of the addition of vitamin K antagonists to dual anti-platelet therapy in patients with PCI-treated STEMI and LV thrombus formation

Study design

A multicenter, prospective, randomized, non-inferiority trial with blinded evaluation of endpoints

Intervention

After written informed consent has been obtained, echocardiography and MRI are performed within 8 weeks after PCI. When LV thrombus is present on baseline MRI, patients are randomized to
1) Triple antithrombotic therapy (aspirin (100 mg/d), thienopyridine class antiplatelet agent, e.g. clopidogrel (75 mg/d) and vitamin K antagonist (goal INR is 2.0 to 3.0))
2) Dual anti-platelet therapy (aspirin (100mg/d) and thienopyridine class antiplatelet agent, e.g. clopidogrel (75 mg/d).

Study burden and risks

high bleeding risk with triple anti-thrombotic therapy versus higher risk trombolic complications dual anti-platelet therapy

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

1.Suspected LV thrombus on echocardiography or routine MRI ;2.Ongoing treatment with dual antiplatelet therapy (e.g. ASA and clopidogrel) at the time of;randomization

Exclusion criteria

The following exclusion criteria are applied:;1 Younger than 18 ;2 Clinically or hemodynamically unstable;3 Treatment with vitamin K antagonist prior to PCI or other expected indication for vitamin K antagonist treatment (e.g. atrium fibrillation) within the next 6 months;4 Previous stroke or transient ischemic attack ;5 Scheduled for major surgery (including CABG) during the course of the study;6 Active bleeding or high risk for bleeding contraindicating treatment with vitamin K antagonists;7 Contra-indication for vitamin K treatment;8 Chronic treatment with NSAIDs or COX-2 inhibitors for more than 4 days per week anticipated to continue during the study;9 Congenital cardiac disease;10 Presence of supraventricular or ventricular arrhythmias;11 Expected candidate for ICD implantation with the next 6 months;12 Severe renal impairment (estimated glomerular filtration rate (eGFR) <= 30mL/min);13 Known or symptomatic brain disease (e.g. brain tumor);14 Women who are pregnant. ;15 Any contraindication for Contrast-Enhanced Magnetic Resonance Imaging i.e.:;• pacemaker;• cerebrovascular clips ;• known contrast allergy;• claustrophobia;16 Follow-up impossible (no fixed abode, etc)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2012
Enrollment:	650
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Marcoumar
Generic name:	Phenprocoumon
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sintrom
Generic name:	Acenocoumarol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	18-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	24-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2013
Application type:	Amendment
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
EudraCT	EUCTR2011-004265-32-NL
CCMO	NL37573.018.11