Acute and chronic administration of the folate derivate levofolinate to patients with acute myocardial infarction: A double-blinded placebo-controlled pilot study.
"Folate in Acute Myocardial Infarction (FolAMI-study)"

Published: 09-10-2009
Last updated: 04-05-2024

A controlled trial to investigate whether by reducing eNOS uncoupling, by direct super oxide scavenging and by up regulating the high-energy phosphate pool, a high dose of intravenous levofolinate can reduce ischemia- and reperfusion-induced...

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON33443

Source
ToetsingOnline

Brief title
FolAMI-study, Folate in Acute Myocardial Infarction.

Condition

- Myocardial disorders

Synonym
acute myocard infaction, heart infartion

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Merck Eprova Suisse,Merck Eprova Suisse: ondersteunt onderzoek op AZM en CARIM omtrent de cardioprotectiev effecten van folate-derivaten.

Intervention

Keyword: Acute Myocardial Infarction, Folate, Myocardial and endothelial function, ST-elevation

Outcome measures

Primary outcome

Main study parameter/endpoint

The primary endpoints of this double-blinded, placebo-controlled randomized

Intervention Study with a monocentric location will improvement of endothelial

and myocardial function.

Secondary outcome

Secondary study parameters/endpoints

Infarct size, CK-MB and troponine releases, TIMI-bloodflow, ST-segment

resolution and the incidence of reperfusion-induced arrhythmia will be

investigated as secondary endpoints.

Study description

Background summary

LevoFolinate can become an attractive therapeutic target to reduce
eNOS-dependent ROS generation e.g. during ischemia- and reperfusion-induced

myocardial damage in patients with an acute myocardial infarction.

Study objective

A controlled trial to investigate whether by reducing eNOS uncoupling, by direct super oxide scavenging and by up regulating the high-energy phosphate pool, a high dose of intravenous levofolinate can reduce ischemia- and reperfusion-induced myocardial damage (cell-death, endothelial dysfunction, myocardial function and arrhythmia).

Study design

A double-blinded placebo-controlled pilot study of acute and chronic administration of levofolinate (folinic acid) to patients with an acute myocardial infarction.

Intervention

one time IV foliumzuur, than once daily oral, one capsule.

Study burden and risks

Not applicable

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

typical retrosternal pain with electocardiographic evidence for ST-elevated myocardial infarction (STEMI)
· Time onset angina pectoris - emergency room:<4h
· Age between 35-75 y
· Coronarographic proof of occluded/critical LAD-lesion
· Successful reperfusion (TIMI >= 2) after dilation and stent placing of culprit LAD-lesion

Exclusion criteria

· Patients with pernicious anemia or other megaloblastic anemia*s where vitamin B12 is deficient.
· Patients using phenobarbitone, phenytoin and primidone
· Phenylketonuria
· Exogenous administration of FA or multivitamin pills with FA >= 400µg
· Oncologic medical history with methotrexate administration
· Coronary ischemia from other reasons than atheromatose (eg. low-output syndrome, anaemia, drug-abusus)
· Hemodynamic Unstable patients (need for inotropica, IABP)
· Bradycardia (heart rate <40 beats/min).
· 3-vessel disease with prospection of CABG in the following 4m
· Medical history of immunosupression or seizures
· Reduced prognosis due to pre-existing comorbidity
· HCG-positivity or pregnancy-wish
· Administration of thrombolytica (full dose and/or bolus)
· Kidney Failure (GFR<20ml/min)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	71
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	09-10-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2009-012526-36-NL
CCMO	NL28052.068.09