A single ascending dose, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of MDCO-216 infusion in healthy volunteers and in patients with known stable coronary artery disease

Published: 29-11-2012
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Primary objective: To investigate the safety, tolerability and pharmacokinetics of escalating single doses of MDCO-216 in healthy volunteers and in patients with known stable coronary artery disease.Secondary objective: To characterize the...

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

Summary

ID

NL-OMON39847

Source
ToetsingOnline

Brief title
MDCO-216 in healthy volunteers & patients with proven stable CAD

Condition

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

Synonym
atherosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Medicines Company
Source(s) of monetary or material Support: The Medicines Company Inc

Intervention

Keyword: Apo-AI Milano, HDL cholesterol, Kinetics, Patients with CAD

Outcome measures

Primary outcome

Safety, tolerability and pharmacokinetics of escalating single doses of

MDCO-216

Secondary outcome

Pharmacodynamics effects of a single dose of MDCO-216 on plasma lipid profiles

including free cholesterol and exploratory measures of cholesterol efflux.

Study description

Background summary

MDCO-216 is being developed as a disease-modifying treatment for patients with atherosclerotic disease and acute coronary syndrome (ACS) to limit disease progression by reducing cholesterol deposition in arterial walls and reduce the occurrence of atherothrombotic events. MDCO-216 mimics high density lipoprotein cholesterol (HDL) in structure and function and has been shown to promote the removal of cholesterol from atherosclerotic plaques in animal studies. Earlier clinical studies with a comparable compound demonstrated that HDL-mimetica have the capability to decrease plaque volume in coronary artery atherosclerotic plaques.

Study objective

Primary objective: To investigate the safety, tolerability and pharmacokinetics of escalating single doses of MDCO-216 in healthy volunteers and in patients with known stable coronary artery disease.
Secondary objective: To characterize the pharmacodynamics effects of a single dose of MDCO-216 in healthy volunteers and in patients with known stable coronary artery disease as measured by effects on plasma lipid profiles including free cholesterol and exploratory measures of cholesterol efflux.

Study design

I: Five (5) parallel cohorts of healthy volunteers who will be given single ascending doses of MDCO-216 or placebo (active:placebo 3:1)
II: Four (4) parallel cohorts of patients with proven, stable CAD who will be given single ascending doses of MDCO-216 or placebo (act=4: plac:2)

Intervention

IV administration of single ascending dose of MDCO-216 or placebo

Study burden and risks

Burden: medical screening ; 2 days admitted to clin research unit for dosing, measurements en sampling; follow-up visits
Risk: unknown adverse events that were not identified in pre-clinical experiments

Contacts

Public
Medicines Company

Sylvan Way 8
Parsippany NJ 07054
US
Scientific
Medicines Company

Sylvan Way 8
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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy volunteers:
Males or females, 18-55 years of age, without clinically significant abnormalities who are willing and able to give informed consent before initiation of any study related procedures and willing to comply with all required study procedures;Patients
Male or female patients 45 - 80 years of age with proven stable atherosclerotic coronary artery disease who are willing and able to give informed consent before initiation of any study related procedures and willing to comply with all required study procedures

Exclusion criteria

Healthy volunteers:
Use of medication or over-the-counter substances; any surgical or medical condition which, in the judgment of the Investigator, might interfere with the pharmacokinetics, distribution, metabolism, or excretion of the study drug.;Patients:
Myocardial infarct within the last 6 months; Any percutaneous revascularization within the last 6 months; Cerebral ischemic event defined as stroke or transient ischemic attack within the last 1 year; any surgical or medical condition which, in the judgment of the Investigator, might interfere with the pharmacokinetics, distribution, metabolism, or excretion of the study drug.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2013
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-01-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-06-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2012-004370-26-NL
CCMO	NL42519.056.12