A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Evaluating the Efficacy and Safety of Alirocumab in Patients with Primary Hypercholesterolemia Not Treated With a Statin

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41636

Source
ToetsingOnline

Brief title
ODYSSEY CHOICE II

Condition

- Other condition

Synonym
high cholesterol, hypercholesterolemia

Health condition

hypercholesterolemie

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Sanofi

Intervention

Keyword: efficacy, Hypercholesterolemia, safety, statin intolerant

Outcome measures

Primary outcome

The percent change in calculated LDL-C from baseline to week 16.

Secondary outcome

The percent change in LDL-C from baseline to week 12.

The percent change of other lipid parameters from baseline to week 12, week 16

and week 24.

Study description

Background summary

Hypercholesterolemia, particularly an increase in low-density lipoprotein cholesterol (LDL-C) levels, constitutes a major risk for the development of atherosclerosis and coronary heart disease (CHD). Current LDL-C lowering medications include statins, ezetimibe (EZE), fibrates, niacin, and bile acid sequestrants. While statins are proven to be well tolerated agents there is a subset of patients who are intolerant to statin therapy and/or who suffer from side effects. Sanofi is developing a new drug to lower LDL-cholesterol, alirocumab. Alirocumab blocks PCSK9 binding to the LDL-receptor, which can potentially benefit patients with hypercholesterolemia by decreasing their plasma LDL-C levels.

Study objective

The primary objective of the study is to demonstrate the reduction of low-density lipoprotein cholesterol (LDL-C) by a regimen including an alirocumab starting dose of 150 mg Q4W as add-on to non-statin lipid modifying background therapy or as monotherapy in comparison with placebo in patients with primary hypercholesterolemia not treated with a statin.

Study design

A randomized, double-blind, placebo-controlled, parallel-group study.

Intervention

- Alirocumab 150 mg every 4 weeks
- Alirocumab 75 mg every 2 weeks
- Placebo every 2 weeks

Study burden and risks

The most common side effects of alirocumab reported in previous completed studies of alirocumab in patients who received at least one dose of alirocumab include: injection site reactions, dizziness, headache, nausea and diarrhea.

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

Patients with primary hypercholesterolemia (heFH or non-FH) not adequately controlled with their non statin lipid modifying therapy or diet.

Exclusion criteria

- LDL-C < 70 mg/dL (1.81 mmol/L) and very high cardiovascular (CV) risk patients who are intolerant to statins at the screening visit
- LDL-C < 100 mg/dL (< 2.59 mmol/L) and at high or moderate CV risk patients at the screening visit
- Patients not fulfilling the statin intolerant definition and at moderate CV risk with LDL-C < 100 mg/dL (<2.59 mmol/L) at the screening visit
- LDL-C >= 160 mg/dL (>= 4.1 mmol/L) if receiving diet only

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2014
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not available yet
Generic name:	alirocumab

Ethics review

Approved WMO Date:	27-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	12-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	10-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2016
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	EUCTR2013-002659-14-NL
CCMO	NL46239.018.13
Other	Zie sectie J