A Randomized, Double-Blind, Active-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of SAR236553/REGN727 over 24 weeks in Patients with Hypercholesterolemia

Published: 13-07-2012
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To demonstrate the reduction of low-density lipoprotein cholesterol (LDL-C) by SAR236553 in comparison withezetimibe after 24 weeks of treatment in patients with hypercholesterolemia

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

Summary

ID

NL-OMON36881

Source
ToetsingOnline

Brief title
EFC11716

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, randomised, safety

Outcome measures

Primary outcome

Percent change in LDL-C after 24 weeks

Secondary outcome

Percent change in LDL-C Percent change after 12 weeks

Percent change in other lipid parameters after 24 weeks

Study description

Background summary

A high cholesterol increases the risk of cardiovascular disease. It is therefore important to treat a high cholesterol. Medicines for this already exist, but they know side effects and do not always have enough effect. Sanofi is therefore developing a new drug to lower cholesterol, SAR236553. We will test this drug in this trial. It may help to lower patient*s cholesterol alone or in combination with other drugs in the future.

Study objective

To demonstrate the reduction of low-density lipoprotein cholesterol (LDL-C) by SAR236553 in comparison with
ezetimibe after 24 weeks of treatment in patients with hypercholesterolemia

Study design

The EFC11716 study is A Randomized, Double-Blind, Active-Controlled,

Parallel-Group Study

Intervention

Group SAR236553
• SAR236553 by injection every two weeks (75 of 150mg)
• placebo ezetimibe (capsule, orally), once daily.

Group Ezitimibe
• ezetimibe (capsule, orally), once daily
• placebo SAR236553 by injection every two weeks (75 of 150mg)

Study burden and risks

SAR236553
The most common side effects reported in previous completed studies of SAR236553 in patients who received at least one dose of SAR236553 include: injection site reactions, dizziness, headache, nausea and diarrhea.

Ezetimibe:
abdominal pain, diarrhea, flatulation and feeling tired

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 hypercholesterolemia at moderate cardio-vascular (CV) risk defined with a 10-year risk SCORE >=1% and < 5% based on the Systematic Coronary Risk Estimation (SCORE)

Exclusion criteria

* Age < 18 or legal age of adulthood, whichever is greater
* LDL-C < 100 mg/dL (< 2.59 mmol/L) or > 190 mg/dL (> 4.9 mmol/L)
* Fasting serum TG > 400 mg/dL > 4.52 mmol/L)
* Known history of homozygous or heterozygous familial hypercholesterolemia

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2012
Enrollment:	30

Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	ezetimibe
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	SAR236553
Generic name:	SAR236553

Ethics review

Approved WMO Date:	13-07-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	17-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-05-2013
Application type:	Amendment
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
EudraCT	EUCTR2011-001424-38-NL
ClinicalTrials.gov	NCT01644474
CCMO	NL41278.060.12