Getting to an imprOved Understanding of Low-Density Lipoprotein Cholesterol and Dyslipidemia management (GOULD): a Registry of High Cardiovascular Risk Subjects in the United States

First published: 29/11/2016

Last updated: 19/04/2022

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46756

EU PAS number

EUPAS16291

Study ID

46756

DARWIN EU® study

No

Study countries

United States

Study description

Primary Objective: • Describe low-density lipoprotein (LDL) treatment patterns over time in subjects with clinical atherosclerotic cardiovascular disease (ASCVD) Secondary Objectives: • Describe (LDL-C) levels and measurement patterns in subjects with clinical ASCVD • Describe subject characteristics • Describe subject understanding of CV risk, goals of lipid management and attitudes towards lipid lowering treatment (LLT) Exploratory Objectives: • Estimate the effect of subject, physician, and site factors on LLT patterns • Describe management of statin intolerance • Describe changes in LLT patterns after the release of updated lipid management guidelines and/or new clinical study data

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 120 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/03/2016

Actual: 15/03/2016

Study start date

Planned: 09/12/2016

Actual: 06/12/2016

Data analysis start date

Planned: 22/09/2021

Actual: 30/09/2021

Date of final study report
Planned: 25/03/2022

Actual: 12/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Repatha 20150230 Original Protocol_14AUG2016 redacted 10 17 2016 final for PASS.pdf(1.89 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Describe low-density lipoprotein (LDL) treatment patterns over time in subjects with clinical atherosclerotic cardiovascular disease (ASCVD)

Data collection methods:

Primary data collection

Main study objective:

Describe low-density lipoprotein (LDL) treatment patterns over time in subjects with clinical atherosclerotic cardiovascular disease (ASCVD)

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

This is a multi-centre observational cohort study with both Retrospective and Prospective data collection components in subjects with ASCVD.

Study drug and medical condition

Medical condition to be studied

Dyslipidaemia

Cardiovascular disorder

Population studied

Short description of the study population

The study population will include subjects with ASCVD in the US.

Inclusion Criteria

Subject

- ≥ 18 years of age at signing of informed consent
- at least 1 planned visit in the next 12 months
- available for follow-up questionnaires
- established ASCVD defined as meeting at least 1 of the following criteria:

o coronary artery disease

o prior history of myocardial infarction

o coronary or other arterial revascularization

o ischemic stroke or transient ischemic attack

o documented peripheral arterial disease secondary to atherosclerosis (., aortic aneurysm, ankle brachial index < 0.9, imaging evidence of > 50% stenosis in any peripheral artery, or intermittent claudication)

o carotid artery stenosis

Cohorts

- For the cohort of approximately 500 subjects taking a PCSK9i at baseline: evidence of a current prescription for an approved PCSK9i and subject confirmation that they have taken a PCSK9i within 30 days prior to enrollment
- For the cohort of approximately 2000 subjects with LDL-C ≥ 100 mg/dL at

last measurement: confirmation of LDL-C ≥100 mg/dL with no change in LLT for 4 weeks (statin and other non-statin therapies). For the cohort of approximately 2500 subjects with LDL-C 70-99 mg/dL at last measurement: confirmation of LDL-C 70-99 mg/dL with no change in LLT for 4 weeks

Exclusion Criteria

Subject

- Unable or unwilling to provide informed consent including but not limited to cognitive or language barriers
- Current or planned participation in an interventional clinical study involving any investigational medical device or drug treatment at the time of enrollment
- Life expectancy <12 months
- Currently pregnant, breast feeding, or planning to become pregnant*

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Atherosclerotic cardiovascular disease patients

Estimated number of subjects

5000

Study design details

Outcomes

• changes in LLT • initiating or discontinuing statin therapy • increasing or decreasing the dose of a statin • switching to a different statin • initiating or discontinuing ezetimibe • initiating or discontinuing a PCSK9i • increasing or decreasing the dose of a PCSK9i • switching to a different PCSK9i • change in other LLT (defined as BAS, prescription LLT, mipomersen, lomitapide, • whether or not LDL-C (mg/dL) and other lipid values as measured, and if so, date and value (mg/dL) • Physician-level Questionnaire • lipid treatment objective in subjects with ASCVD o lower LDL-C o manage other lipid parameters o treating subjects with any dose of statin therapy o treating subjects with maximally tolerated statin therapy o reduce CV risk o other • Subject -level

Data analysis plan

A baseline analysis will be conducted after the last subject enrolled. Additional data analyses will be conducted on periodic basis throughout study period.

Documents

Study results

20150230 ORSR Abstract_Redacted.pdf(958.74 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective and Prospective data will be provided by study site staff, utilizing subject charts to abstract information in order to complete eCRFs in the study-specfic electronic database. Data from physician and subject questionnaires will be collected in a database that is separate from that at the sites.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No