A drug utilization study (DUS) of alirocumab in Europe to assess the effectiveness of the dosing recommendation to avoid very low LDL-C levels

First published: 17/10/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21314

Study ID

43665

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

This is a drug utilization study to evaluate the effectiveness of the alirocumab dosing recommendations for the 3 approved dosage regimens to date, ie, 75 mg every two weeks, 150 mg every two weeks, and 300 mg once every 4 weeks (monthly) to avoid very low LDL C levels. The secondary objective is to describe the pattern of alirocumab utilization in real-world clinical practice with respect to the dosing recommendations in the labelling of the 3 approved dosage regimens to date, ie, 75 mg every two weeks, 150 mg every two weeks, and 300 mg once every 4 weeks (monthly) to avoid very low LDL-C levels.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team Contact-Us@sanofi.com

Study contact

Contact-Us@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/11/2017

Actual: 06/11/2017

Study start date

Planned: 30/03/2018

Actual: 20/08/2019

Date of final study report
Planned: 30/09/2021

Actual: 10/08/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi/Regeneron

Study protocol

rdct-obs14697-16-1-1-pass-amended-protocol02-PDFA.pdf (839.92 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

OBS14697

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to assess the effectiveness of the dosing recommendations for the 3 approved dosage regimens to date. The secondary objective is to describe the pattern of alirocumab utilization in real-world clinical practice

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PRALUENT

Population studied

Short description of the study population

Patients who were initiated with Praluent (brand name of alirocumab), 75 mg once every two weeks, 150 mg once every two weeks, or 300 mg once every 4 weeks (monthly).

Inclusion criteria

Physicians who meet the following inclusion criterion will be eligible to participate in this study:

I 01. At least one initial prescription of Praluent during the eligibility period.

Eligible patients for retrospective data collection will be those meeting the following criteria:

I 02. Initiated with Praluent following a first prescription during the eligibility period.

I 03. Signed written informed consent, if it is required by the country.

Exclusion criteria

Physicians who meet one or more of the following exclusion criteria will be excluded from this study:

E 01. Have participated in any randomized clinical trials with Praluent (alirocumab).

E 02. Have participated in a previous wave of this study.
Patients who meet one or more of the following exclusion criteria will be excluded from this study:
E 03. Have participated in any randomized clinical trials with Praluent (alirocumab).
E 04. Medical chart not retrievable, empty or missing

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)

Estimated number of subjects

890

Study design details

Outcomes

- Occurrence of very low LDL-C levels (both definitions of very low LDL-C <25 mg/dL 0.65 mmol/L and <15 mg/dL 0.39 mmol/L will be presented), - Evolution of LDL-C level after the occurrence of very low LDL-C level, - Change in treatment after the occurrence of very low LDL-C level. - The starting dose of Praluent, - The dosage regimen modification of Praluent, - Timing of LDL-C tests, - Discontinuation of Praluent: reasons will be described, if available, - Reason for Praluent prescription, - Adverse events.

Data analysis plan

The following descriptive analyses will be presented on the eligible population: A. Occurrence of very low LDL-C level A LDL-C level <25 mg/dL (0.65 mmol/L) is defined as very low, and an alternative definition with a cut-off at 15 mg/dL (0.39 mmol/L) will also be used. B. Evolution of LDL-C level after the occurrence of very low LDL-C level C. Change in treatment after the occurrence of very low LDL-C level

Documents

Study results

rdct-obs14697-CSR synopsis-PDFA.pdf (331.56 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Data from medical records (either EMRs or paper source files) for each participating patient will be extracted and completed by site personnel and/or trained and authorized external abstractors using an e-CRF.

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