Monitoring the safety of alirocumab in HIV patients: A Post-Authorization Safety Study Using Healthcare Databases

First published: 17/01/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49411

EU PAS number

EUPAS17314

Study ID

49411

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study is a retrospective cohort study using existing healthcare databases.The objective of this post-marketing study is to monitor muscle events, and liver function and creatine kinase abnormalities in HIV patients treated with alirocumab by quantifying the incidences of these safety outcomes using existing healthcare databases.Two databases, the Clinformatics DataMart and the MarketScan databases in the US, will be used in this study. The study period will be from July 25, 2015 to September 30, 2020. The main study cohort will consist of new users of alirocumab with HIV infection during the study period. The comparison cohort will consist of new users of a statin or ezetimibe with HIV infection. Patients will be followed till the occurrence of outcomes of interest, which are -Serious muscle events, abnormal liver function and abnormal creatine kinase values, end of index treatment episode, end of eligibility in the database, or end of the study period. For each outcome of interest, the incidence rate (cases per 1,000 person-years) and their 95% confidence intervals (CI) will be calculated for the matched cohorts.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team

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: 21/12/2015

Actual: 21/12/2015

Study start date

Planned: 30/09/2017

Actual: 30/09/2017

Date of final study report

Planned: 30/09/2022

Actual: 29/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi and Regeneron

Study protocol

rdct-aliroc07997-protocol-pdfa.pdf(499.31 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

ALIROC07997

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective of this post-authorization safety study is to monitor muscle events, and liver function and creatine kinase abnormalities in HIV patients treated with alirocumab by assessing the incidences of these safety outcomes using existing healthcare databases.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ALIROCUMAB

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

Adult patients with HIV infection receiving alirocumab and other lipid-lowering treatments identified from the study period of 25 July 2015, utilizing data source from the Optum Clinformatics DataMart (Optum CDM) and the Truven Health Marketscan (Marketscan).

Inclusion criteria:

• A new prescription of a statin or ezetimibe in the study period

• HIV infection confirmed by the presence of relevant diagnosis codes (Appendix 1) prior to the index date

Exclusion criteria:

• Age < 18 years

• No continuous enrollment with prescription and medical coverage in the database for the 180-day period prior to the index date

• Use of the same index drug prior to the index date

• Use of any PCSK-9 inhibitors prior to the index date

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

Immunocompromised

Estimated number of subjects

765

Study design details

Outcomes

Serious muscle events: rhabdomyolysis, myositis and myopathy Abnormal liver function: ALT and AST elevation > 5 times above the upper limit of normal value, total bilirubin and alkaline phosphatase elevation > 2 and > 1.5 times above the upper limits of normal value, respectively Abnormal creatine kinase: elevation > 10 times above the upper limit of normal value

Data analysis plan

Patients in the alirocumab cohort and those in the other lipid-lowering drug cohort will be matched on the propensity of being treated with alirocumab at a 1:1 ratio using greedy matching. Proportion and means will be used to summarize the categorical and continuous variables (demographic and baseline characteristics), respectively, for the alirocumab and the other drug cohorts both prior to and after the propensity matching. For each outcome of interest, the overall incidence rate (cases per 1,000 person-years) and its 95% confidence interval (CI) in each database will be calculated using the data of the matched cohorts. Kaplan-Meier curves will be used to display the risk of each outcome over time.

Documents

Study results

rdct-aliroc07997-csr abstract-pdfa.pdf(235.35 KB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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