EU-Wide Cross-Sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care DA VINCI

First published: 06/02/2018

Last updated: 19/09/2019

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31479

EU PAS number

EUPAS22075

Study ID

31479

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Belgium
- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Romania
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Ukraine
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Amgen

Multiple centres: 153 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: 17/11/2016

Actual: 17/11/2016

Study start date

Planned: 01/06/2017

Actual: 01/06/2017

Data analysis start date

Planned: 22/02/2019

Actual: 22/02/2019

Date of final study report

Planned: 19/09/2019

Actual: 16/08/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Ltd.

Study protocol

EUPAS22075-23671.pdf(832.58 KB)

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Characterise unmet medical need

Data collection methods:

Secondary use of data

Main study objective:

To estimate the proportion of subjects in EU primary and secondary care, with or without established ASCVD and receiving LMT, with LDL-C above 2016 Joint ESC Guideline recommended levels

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

REPATHA

Medical condition to be studied

Ischaemic stroke

Myocardial infarction

Peripheral vascular disorder

Hypercholesterolaemia

Population studied

Short description of the study population

1. Low density lipoprotein-cholesterol (LDL-C) measurement within 14 months of enrolment, obtained independently of participation in a clinical trial
2. Use of any LMT (may include statin/ezetimibe/fibrate/PCSK9 inhibitor/bile acid absorption inhibitor/nicotinic acid/other) at time of enrolment, or any LMT

prescribed within 12 months prior to date of enrolment, or any LMT prescribed at date of enrolment

3. Age 18 years or older at enrolment

4. Provided informed consent/notified according to local requirements

5. Subject expected to survive for at least 1 year after enrolment

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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

6000

Study design details

Outcomes

LDL-C measurement most recent to enrolment, Lipid levels (total cholesterol, non-HDL-C, HDL, triglycerides, Lp(a), apo B100, apo A1) most recent to enrolment, use of Lipid-modifying therapy (type, dose, frequency), clinical characteristics at time of enrolment

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Data analysis plan

All summaries of data will be descriptive in nature: categorical variables in frequency and percentage with 95% confidence intervals and continuous variables in mean (standard deviation) and/or median with percentiles, minimum and maximum.

Documents

Study results

20150333_DA VINCI FINAL ORSR abstract 16AUG19 incl PI signature - 120919_redacted.pdf(407.3 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Medical notes (primary and secondary care)

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