RETrospective Observational Study of Evolocumab Use in Spanish Endocrinology Units (RETOSS-Endo) (20160140)

First published: 04/08/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20043

Study ID

31421

DARWIN EU® study

No

Study countries

☐ Spain

Study description

RETrospective Observational Study of Evolocumab Use in Spanish Endocrinology Units to describe the main clinical characteristics (LDL-C levels, Diabetes status, FH status prior to treatment initiation) of patients with hyperlipidemia initiating evolocumab in Hospital Endocrinology Units.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 21 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

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: 01/09/2017

Actual: 01/09/2017

Study start date
Planned: 15/09/2017

Actual: 14/09/2017

Data analysis start date
Planned: 30/04/2018

Actual: 17/09/2018

Date of final study report
Planned: 28/08/2019

Actual: 27/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160140_01.02.06 Public Redacted Protocol Ver 1.0 2017-04-21 English.pdf
(338.04 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

The clinical characteristics of patients initiating evolocumab in Spanish Hospital Endocrinology Units, and how is their clinical management

Data collection methods:

Secondary use of data

Main study objective:

To describe the main clinical characteristics of patients with hyperlipidemia initiating evolocumab in Hospital Endocrinology Units

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Observational Study

Study drug and medical condition

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

EVOLOCUMAB

Medical condition to be studied

Hyperlipidaemia

Population studied

Short description of the study population

Patients with hypercholesterolemia, who initiated evolocumab as part of routine clinical management of their hyperlipidaemia, from February 1st, 2016 to April 30th 2017, by an specialist in an Hospital Endocrinology Unit in Spain.

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

Patients with hyperlipidaemia

Estimated number of subjects

150

Study design details

Outcomes

LDL-C pre-initiation of evolocumab, Diabetes status at evolocumab initiation, year of diagnosis, insulin and/or oral hypoglycemic treatment, retinopathy, diabetic nephropathy or diabetic foot), FH status at evolocumab initiation, Demographic and clinical variables at evolocumab initiation, Family medical history at evolocumab initiation, Medical history and CV risk at evolocumab initiation, Laboratory parameters over time, Clinical Factor/s that determined evolocumab prescription at initiation, use of evolocumab and other lipid-lowering therapies over time

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Data analysis plan

Analyses will be performed on all included subjects who fulfill all the selection criteria. All summaries of the data will be descriptive in nature. For categorical variables the frequency and percentage, with 95% confidence interval, will be given.Summary statistics for continuous variables will include the number of subjects, mean, median, standard deviation or standard error, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum.For the outcome measure of LDL-C and other laboratory values over time, the data will be assigned to predefined time-points according to specific windows detailed in the protocol.Statistical analyses will be descriptive only. No statistical inference or imputations of missing data are planned.

Documents

Study results

RETOSS-Endo (AMG1092)_CSR_Final_Abstract.pdf(118.31 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

Patient notes from Endocrinology Units

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