

# 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

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### Study ID

31421

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### DARWIN EU® study

No

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### Study countries

 Spain

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### 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.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Amgen

 United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

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](mailto: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

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**Study start date**

Planned: 15/09/2017

Actual: 14/09/2017

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**Data analysis start date**

Planned: 30/04/2018

Actual: 17/09/2018

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**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

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**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

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**Study type:**

Non-interventional study

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**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

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**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

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**Non-interventional study design, other**

Retrospective Observational Study

## Study drug and medical condition

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

EVOLOCUMAB

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## **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.

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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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with hyperlipidaemia

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### **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)

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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](#)

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No