Drug utilisation and patient characterisation of statin usage

First published: 06/10/2025

Last updated: 06/10/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000764

Study ID

1000000764

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] United Kingdom

Study description

A simple descriptive study to measure the incidence of exposure to statin therapy in primary care and treatment characterisation.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/06/2024

Actual: 11/06/2024

Study start date

Planned: 11/06/2024

Actual: 11/06/2024

Date of final study report

Planned: 28/02/2025

Actual: 17/09/2025

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

Study type:

Non-interventional study

Study design:

Cohort and drug utilisation study covering the study period 2010 to 2023

Main study objective:

Objective 1: Incidence of prescriptions

1a. What was the annual incidence of the prescription of individual statins and any statin, stratified by age group and sex?

1b. What were the lines of therapy for incident statin users? I.e. what were the proportions of first, second and third line of treatment?

Objective 2: Characterisation of statin users

2a. What was the duration (mean, SD) of continuous individual statin and any statin prescriptions (non-incident), stratified by age, sex, or cardiovascular diagnosis?

2b. What were the most common cardiovascular diagnoses, close to the initiation date, for each of the individual statins, and any statin (non-incident)?

2c. In patients who were prescribed statins in the study period, which earlier statin(s) were they prescribed, up to 1 or 5 years before? And how many?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Statins (HMG-CoA reductase inhibitors ATC C10AA)

Anatomical Therapeutic Chemical (ATC) code

(C10AA) HMG CoA reductase inhibitors

HMG CoA reductase inhibitors

Population studied

Short description of the study population

General primary care population

Study design details

Setting

Primary care

Outcomes

Exposure to Atorvastatin, Fluvastatin, Lovastatin (IQVIA DA DE only), Pitavastatin (IQVIA DA DE only), Pravastatin, Rosuvastatin, Simvastatin.

Documents

Study report

Report-Dus and patient characterisation of statin usage.pdf (2.46 MB)

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 source(s)

IQVIA Medical Research Data - OMOP

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No