# Cost-Effectiveness Analysis of Treatment with Statins in Primary Prevention of Vascular Events (EPREV project)

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# Administrative details

**Study description** 

<b>EU PAS number</b> EUPAS4085	
Study ID 4086	
DARWIN EU® study	
Study countries  Spain	

Objectives: 1. To Analyze the cost-effectiveness of statins treatment by different baseline cardiovascular risk strata. 2. To analyze the costeffectiveness of statins therapy according to baseline cholesterol and total cholesterol reduction. 3. Set breakpoints based on the baseline cardiovascular risk, cholesterol and basal absolute reduction of cholesterol on the basis of the cost-effectiveness. Subjects: People without a history of vascular events receiving treatment in any public Primary Care Centre (Institut Català de la Salut). Data will be obtained from the Information System for the Development of Primary Care Research (SIDIAP) whose primary source of data are electronic medical records (e-CAP) and other data sources, such as CATSALUT's invoice offices pharmacy and the Minimum Basic Data Set (CMBD). Methodology: The design consists of two parts: firstly, from a matched cohort on the basis of propensity score, we will estimate the following parameters: 1. incidence density of cardio and cerebrovascular events, 2. population risk factors prevalence for baseline cardiovascular risk calculations, 3. Markov model utilities. The study will include approximately 83,500 new users of statins in the period of the study and a ratio of at least 3 controls per case (250,000 persons in the unexposed group). The follow-up period will be four years. Subsequently, we will build a Markov model for cost-utility analysis from cohort data and data on costs from the perspective of the NHS. The analysis will be performed based on the ratio of incremental cost-effectiveness (ICER).

#### **Study status**

Finalised

Research institutions and networks

Institutions

# Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol Spain First published: 05/10/2012 Last updated: 23/05/2025 Institution Educational Institution Laboratory/Research/Testing facility Not-for-profit ENCePP partner

#### Contact details

#### **Study institution contact**

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Study contact

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## **Primary lead investigator**

Maria Garcia

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 01/01/2010

Actual: 01/01/2010

#### Study start date

Planned: 01/04/2010 Actual: 01/12/2010

#### **Date of final study report**

Planned: 31/12/2013 Actual: 03/04/2013

# Sources of funding

Other

# More details on funding

Health Ministry

# Regulatory

Was the study required by a regulatory body?

No

# Methodological aspects

Study type

Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Effectiveness study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

1. To Analyze the cost-effectiveness of statins treatment by different baseline cardiovascular risk strata. 2. To analyze the cost-effectiveness of statins therapy according to baseline cholesterol and total cholesterol reduction. 3. Set breakpoints based on the baseline cardiovascular risk, cholesterol and basal absolute reduction of cholesterol on the basis of the cost-effectiveness

# Study Design

Non-interventional study design

Cohort

# Study drug and medical condition

Medical condition to be studied

Acute myocardial infarction
Ischaemic stroke
Coronary revascularisation
Peripheral revascularisation

# Population studied

#### Short description of the study population

People without a history of vascular events receiving treatment in any public Primary Care Centre (Institut Català de la Salut)

#### Age groups

- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)

#### **Estimated number of subjects**

100000

# Study design details

#### **Outcomes**

Acute myocardial infarction, ischemic stroke, coronary revacularization procedures, cardiovascular and global mortality, Statin adverse effects

#### **Data analysis plan**

Methodology: The design consists of two parts: firstly, from a matched cohort on the basis of propensity score, we will estimate the following parameters: 1. incidence density of cardio and cerebrovascular events, 2. population risk factors prevalence for baseline cardiovascular risk calculations, 3. Markov

model utilities. The study will include approximately 83,500 new users of statins in the period of the study and a ratio of at least 3 controls per case (250,000 persons in the unexposed group). The follow-up period will be four years. Subsequently, we will build a Markov model for cost-utility analysis from cohort data and data on costs from the perspective of the NHS. The analysis will be performed based on the ratio of incremental cost-effectiveness (ICER).

# 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)

The Information System for Research in Primary Care (SIDIAP)

#### Data source(s), other

**SIDIAP** 

#### Data sources (types)

Other

#### Data sources (types), other

Prospective patient-based data collection

## 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