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

First published: 06/06/2013

Last updated: 06/06/2013

Study Finalised

Administrative details

EU PAS number

EUPAS4085

Study ID

4086

DARWIN EU® study

No

Study countries

Spain

Study description

Objectives: 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. 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

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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)
- Adults (65 to < 75 years)

Estimated number of subjects

100.000

Study design details

Outcomes

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

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Data analysis plan

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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