Measurement of the effectiveness of statins in vascular morbidity and mortality reduction in the population without history of vascular disease but with intermediate risk and ankle-brachial Index < 0.9 in primary care setting (MARIA study)

First published: 06/06/2013

Last updated: 06/06/2013

Study Finalised

Administrative details

EU PAS number

EUPAS4088

Study ID

4089

DARWIN EU® study

No

Study countries

Spain

Study description

Objective: To evaluate the effectiveness of statin therapy to reduce the incidence of vascular disease in patients with unknown history of vascular disease with intermediate cardiovascular risk (5-15% at 10 years) and abnormal ankle-brachial index (<0.9). Design: Population matched cohort on the basis of propensity score. Data were obtained from the Information System for the Development of Primary Care Research whose primary source of data is the the electronic health records (e-CAP) of the Institut Català de la Salut. Subjects: Population from 35 to 74 years without known vascular disease and with intermediate cardiovascular risk and ankle-brachial index <0.9 (3684 subjects in exposed cohort and 7368 in unexposed cohort). The recruitment period will be guarantee at least 3 years of follow-up. Variables: New statin users are defined according to the criteria of compliance (> 80%) and persistence (> 6 months) and with no invoicing data in the six months before the entry of the cohort. Outcomes: incidence of major cardiovascular events defined as cerebrovascular disease (fatal or not), myocardial infarction (fatal or not), unstable angina, revascularization, intermittent claudication, peripheral arterial disease diagnosis or gangrene and amputation. Moreover, death from any cause will be registered. Independent variables: demographic variables, presence of risk factors, other comorbidities, complementary tests and other drug treatments. Statistical analysis: Time varying Cox regression models will be performed to estimate the incidence of outcomes of interest adjusted for the variable start of treatment and dose (time-dependent variables) and other variables associated with the occurrence of vascular events. We will also calculate estimates of risk reduction and the number needed to treat.

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

Rafel Ramos

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: 05/05/2013

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:

Objective: To evaluate the effectiveness of statin therapy to reduce the incidence of vascular disease in patients with unknown history of vascular disease with intermediate cardiovascular risk (5-15% at 10 years) and abnormal ankle-brachial index (<0.9).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute myocardial infarction

Ischaemic stroke

Coronary revascularisation

Population studied

Short description of the study population

Population from 35 to 74 years without known vascular disease and with intermediate cardiovascular risk and ankle-brachial index < 0.9.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

6000

Study design details

Outcomes

Acute myocardial infarction, stroke, coronary revascularization, cardiovascular and global mortality, statin adverse effects

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Data analysis plan

Design: Population matched cohort on the basis of propensity score. Data were obtained from the Information System for the Development of Primary Care Research whose primary source of data is the the electronic health records (e-CAP) of the Institut Català de la Salut. Subjects: Population from 35 to 74 years

without known vascular disease and with intermediate cardiovascular risk and ankle-brachial index <0.9 (3684 subjects in exposed cohort and 7368 in unexposed cohort). The recruitment period will be guarantee at least 3 years of follow-up. Statistical analysis: Time varying Cox regression models will be performed to estimate the incidence of outcomes of interest adjusted for the variable start of treatment and dose (time-dependent variables) and other variables associated with the occurrence of vascular events. We will also calculate estimates of risk reduction and the number needed to treat.

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)

Electronic healthcare records (EHR)

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