

Comparison of care use between cohorts differentiated by the patients adherence to statins in France between 2005 and 2008 (C2STAT)

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/15439>

EU PAS number

EUPAS5275

Study ID

15439

DARWIN EU® study

No

Study countries

France

Study description

Cardiovascular disease is the leading cause of death worldwide, with about 30 % of deaths. Statins (or HMG -CoA reductase inhibitors) form a class of lipid-lowering drugs, drugs used to lower cholesterol levels in people at risk for cardiovascular disease. Statins are now considered as the most effective therapeutic class for the treatment of hypercholesterolemia. They also demonstrated their beneficial effect on all-cause mortality decrease and on the occurrence of cardiovascular events. Statins are one of the main expenditure for the French health insurance since the early 2000s (1.28 billion euros in 2008). The financial burden associated with statins should remain a major concern in the

coming years, particularly because of the aging population and the increased prevalence of risk factors such as diabetes or obesity, often associated with abnormal lipids. The objective of this study is to compare the use of health care, and the costs associated, with each patient cohorts differentiated by adherence to statin therapy, between 2005 and 2008, based on the French health national insurance database (EGB) which contains healthcare reimbursement data of 1/97 of the French population. The study mainly describes the annualized costs of care use in patients who have had an introduction to statin therapy and compares these costs between three cohorts defined by the level of adherence to statin therapy. It also describes the study population (socio-demographic characteristics, therapeutic profile of patients, characteristics associated with the initiation of statin therapy, level of adherence), identifies factors associated with annualized costs and poor adherence to statins and compare cardiovascular events between the three cohorts defined by level of adherence to statins.

Study status

Finalised

Research institution and networks

Institutions

Université Claude Bernard Lyon 1

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Institution

Contact details

Study institution contact

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Primary lead investigator

Eric VAN GANSE

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:

01/07/2009

Actual:

01/07/2009

Study start date

Planned:

15/07/2009

Actual:

15/07/2009

Data analysis start date

Planned:

15/07/2010

Actual:

02/08/2010

Date of final study report

Planned:

16/09/2011

Actual:

16/09/2011

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

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

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary data collection

Main study objective:

The study describes the annualized costs of care use in patients who have had an introduction to statin therapy and compares these costs between three cohorts defined by the level of adherence to statin therapy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Healthcare cost

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01) ANTITHROMBOTIC AGENTS

(C01D) VASODILATORS USED IN CARDIAC DISEASES

(C02) ANTIHYPERTENSIVES

(C10) LIPID MODIFYING AGENTS

Population studied

Short description of the study population

Patients who have had an introduction to statin therapy.

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)

Estimated number of subjects

5000

Study design details

Outcomes

To describe annualized costs of care use in patients who have had an introduction to statin therapy and to compare these costs between three cohorts defined by the level of adherence to statin therapy. To identify the study population, factors associated with annualized costs and poor adherence to statins and compare cardiovascular events between the three cohorts.

Data analysis plan

A / General description of the study population
B / Description of the level of adherence to statins
C / Description and comparison of annualized costs generated by patients
D / Identification of factors associated with annualized costs
E / Identification of factors associated with poor adherence to statin therapy
F / Comparison of cardiovascular events between the three cohorts defined according to their level of adherence to statins

Data management

Data sources

Data source(s), other

EGB France

Data sources (types)

[Administrative data \(e.g. claims\)](#)

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

Unknown