Observational study of the persistence antiglaucoma eyedrops to

First published: 02/12/2013

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Study Finalised

Administrative details

EU PAS number

EUPAS5312

Study ID

19566

DARWIN EU® study

No

Study countries

☐ France

Study description

Glaucoma is an eye disease leading, if not treated, to progressive, irreversible vision loss. Prevalence of glaucoma in France is around 2% of the population older than 40. Treatment of glaucoma is usually topical ocular hypotensive

medication (eye drops), that should be administered at long term. Adherence, and especially persistence, are essential for the success of the treatment. Non- or poor adherence may induce public health and economic consequences.Persistence under hypotensive eye drops medications in glaucoma management is expected to be rather poor (induced by chronical condition and mode of administration) but is not well documented. This study aims to assess in the french population the persistence under different topical ocular hypotensive medications, based on the French national health insurance database (EGB) which contains healthcare reimbursement data of 1/97 of the French population.The objective of the study is to compare the 12-month persistence under different topical ocular hypotensive medications in glaucoma management. It will include the description and the comparison of persistence in glaucoma management between different topical ocular hypotensive treatments 12 months after treatment initiation, the identification of predictive factors for persistent and non persistent patients and the assessment of the prevalence and incidence of topical ocular hypotensive medications in France from 2005 to 2009.

Study status

Finalised

Research institutions and networks

Institutions

Université Claude Bernard Lyon 1

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Institution

Contact details

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Primary lead investigator

Eric VAN GANSE

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/06/2010

Study start date

Actual: 31/08/2010

Date of final study report

Actual: 31/03/2011

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To compare the 12-month persistence under different topical ocular hypotensive medications in glaucoma management.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(S01EA) Sympathomimetics in glaucoma therapy

Sympathomimetics in glaucoma therapy

(S01EB) Parasympathomimetics

Parasympathomimetics

(S01EC) Carbonic anhydrase inhibitors

Carbonic anhydrase inhibitors

(S01ED) Beta blocking agents

Beta blocking agents

(S01EE01) latanoprost

latanoprost

(S01EE03) bimatoprost

bimatoprost

(S01EE04) travoprost

travoprost

(S01EX) Other antiglaucoma preparations

Other antiglaucoma preparations

Medical condition to be studied

Glaucoma

Population studied

Short description of the study population

French glaucoma patients treated with different topical ocular hypotensive medications identified from French national health insurance database (EGB).

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)

Special population of interest

Other

Special population of interest, other

Glaucoma patients

Estimated number of subjects

5000

Study design details

Outcomes

To define the prevalence and annual incidence of different types of antiglaucoma eyedrops and their respective changes between 2005 and 2010, To study and compare the persistence to 12 months of anti-glaucoma eye drops between major therapeutic classes in France between 2005 and 2010.To study the predictors of persistence for different types of antiglaucoma antiglaucoma eyedrops.

Data analysis plan

A/ Study of the annual prevalence successively from 2004 to 2009,B/ Study the annual incidence successively from 2005 to 2009)C/ Description of the general characteristics of the study population at baselineD/ Description of antiglaucoma eyedrops initiated at T0E/ Description of characteristics related to the initiation of a given classF/ Description and comparison of the persistence rate at 12 months, and identification of factors associated with non-persistenceF-a/ According to the persistent / non-persistent status (binary approach)F-b/ Depending on the time of occurrence of the interruption (survival analysis)G/ Description of coverage in the first 12 months

Documents

Study publications

Belhassen M, Laforest L, Licaj I, Van Ganse E. Early adherence to anti-glaucoma…

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), other

EGB France

Data sources (types)

Administrative healthcare records (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