Observational study of the persistence antiglaucoma eyedrops to

First published: 02/12/2013

Last updated: 30/03/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/19566

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 institution and networks

Institutions

Université Claude Bernard Lyon 1
First published: 01/02/2024
Last updated 01/02/2024
Institution

Contact details

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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 data collection

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
(S01EB) Parasympathomimetics
(S01EC) Carbonic anhydrase inhibitors
(S01ED) Beta blocking agents
(S01EE01) latanoprost
(S01EE03) bimatoprost
(S01EE04) travoprost
(S01EX) 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

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