A population-based cohort study using an existing database to evaluate the association between latanoprost use and primary malignant ocular melanoma and facial cutaneous melanoma

First published: 16/12/2014

Last updated: 29/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/15377

EU PAS number

EUPAS8241

Study ID

15377

DARWIN EU® study

No

Study countries

Sweden

Study description

The primary research aim of this study is to examine the potential association between latanoprost and primary malignant ocular melanoma (OM) and facial cutaneous melanoma (CM), respectively. The secondary research aim is to examine the potential association between prostaglandin analogues (PGAs) and primary malignant OM and facial CM, respectively. A population-based cohort study will be conducted based on secondary use of existing data. The study population will include patients with recorded glaucoma or ocular hypertension (OH) in the Swedish national health care registers from July 1st, 2005 to December 31st, 2011 and with no previous malignant melanoma. Exposure groups (latanoprost, other topical PGAs and topical non-PGAs) will be categorized based on drug exposure data collected from the Swedish Prescription Drug Register (SPDR). Primary malignant OM and facial CM of each patient will be identified from the Swedish Cancer Register (SCR). Cox regression models will be developed to evaluate independent effects of having OM and facial CM, respectively, in association with use of latanoprost and topical PGAs, adjusting for potential confounding variables.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Prethibha George

Study contact

prethibha.george@pfizer.com

Primary lead investigator

Prethibha George

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2013

Actual: 10/06/2013

Study start date
Planned: 15/02/2015

Actual: 05/01/2015

Data analysis start date
Planned: 15/04/2015

Actual: 12/05/2015

Date of final study report
Planned: 30/09/2016

Actual: 09/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

Study protocol

A6111157 Protocol_FINAL_15SEP2013_ENCePP.pdf(464.9 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To examine the potential association between latanoprost and primary malignant ocular melanoma and facial cutaneous melanoma, respectively, using an existing database

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Glaucoma

Intraocular pressure increased

Population studied

Short description of the study population

Patients with recorded glaucoma or ocular hypertension (OH) in the Swedish national health care registers from July 1st, 2005 to December 31st, 2011 and with no previous malignant melanoma history.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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 or ocular hypertension (OH) patients

Estimated number of subjects

116172

Study design details

Outcomes

Ocular melanoma and facial cutaneous melanoma

Data analysis plan

Descriptive statistics will be presented to describe patient characteristics of the latanoprost, other topical Prostaglandin (PGA) and topical non-PGA groups. Incidence rates of primary malignant ocular melanoma (OM) and facial cutaneous melanoma (CM) will be calculated by dividing the number of incident cases of melanoma by the person-time at risk for the appropriate exposure group. Incidence rates of OM and facial CM will be estimated in the latanoprost, other topical PGAs and topical non-PGAs groups. For primary objectives, a change-in-estimate procedure using Cox regression including only exposure and one potential confounder at a time will be conducted to assess the association between latanoprost and covariates and the development of OM and facial CM. Based on these results, a multivariable Cox regression model will be developed to evaluate the independent effect of latanoprost on the risk of primary malignant OM and facial CM while controlling for potential confounding.

Documents

Study results

Latanoprost_OM and Facial CM_FINAL Abstract_Sept 9, 2016.pdf(141.57 KB)

Study report

Latanoprost_OM and Facial CM_FINAL CSR_Sept 9, 2016.pdf(2.07 MB)

Data management

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Swedish Cancer Register Sweden, National Patient Register Sweden, Causes of Death Register Sweden, Longitudinal Population Register on Education, Income and Work Sweden

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

No