# 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

**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 prethibha.george@pfizer.com

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**

**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

## 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)**

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