

# LONG-TERM SURVEILLANCE STUDY OF LATANOPROST TO MONITOR HYPERPIGMENTATION CHANGES IN THE EYE IN PEDIATRIC POPULATIONS

**First published:** 10/03/2014

**Last updated:** 30/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS6023

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### Study ID

38741

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### DARWIN EU® study

No

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### Study countries

☐ Belgium

☐ Colombia

☐ Denmark

- ☐ France
  - ☐ Germany
  - ☐ Greece
  - ☐ Italy
  - ☐ Peru
  - ☐ Portugal
  - ☐ Slovakia
  - ☐ Spain
  - ☐ Sweden
  - ☐ United Kingdom
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### **Study description**

This study is one of the two post-authorization safety studies (PASS) that have been designed to monitor hyperpigmentation changes in the eye for 10 years in pediatric patients treated with latanoprost. The first study is an ongoing cohort study with 3-year follow-up (A6111143) to evaluate the long-term safety profile (including, but not limited to hyperpigmentation changes in the eye) of latanoprost use in pediatric populations. This long-term surveillance study (A6111144) will be initiated by inviting all patients completing the 3-year follow up of the A6111143 study to participate, and hyperpigmentation changes in the eye will be monitored over the subsequent 7-year period. The objective of the A6111144 study is to describe the incidence of hyperpigmentation changes in the eye over a total of 10 years of follow up by combining data collected from the 3-year follow-up in the A6111143 study and the extended 7-year follow-up in the A6111144 study, among pediatric patients with glaucoma or elevated intraocular pressure (IOP). Patients enrolled in the A6111144 study will be classified into the latanoprost exposed, topical prostaglandin analogue (PGA) unexposed, and non latanoprost topical PGA exposed groups. Patients' exposure status, hyperpigmentation change in the eye, basic clinical characteristics (i.e. visual acuity, IOP, optic nerve structure, visual field) will be

obtained at the end of each year for 7 years. Concomitant medications and adverse events will be recorded throughout the study period. Incidence proportions and incidence rates of hyperpigmentation changes in the eye will be calculated for the entire 10 year follow-up period. FSFV of this study is estimated to occur in January 2014 ( $\pm$  2 months) and LSLV is estimated to occur in January 2023 ( $\pm$  2 months). Submission of the final study report will occur within one year after the LSLV (estimated January 2024  $\pm$  2 months).

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Parexel International

☐ United States

**First published:** 19/10/2010

**Last updated:** 10/12/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

**Primary lead investigator**

Arun Kumar

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 28/02/2014

Actual: 28/02/2014

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**Study start date**

Planned: 11/03/2014

Actual: 11/03/2014

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**Data analysis start date**

Planned: 01/02/2023

Actual: 08/05/2023

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**Date of interim report, if expected**

Planned: 31/07/2019

Actual: 03/07/2019

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**Date of final study report**

Planned: 31/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Viatrix Specialty LLC

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

To describe the incidence (proportion and rate) of hyperpigmentation changes in the eye over a total of a 10-year follow-up period by combining the data

collected in the 3-year A6111143 study and the subsequent 7-year A6111144 study, among pediatric patients with glaucoma or elevated intraocular pressure who have completed the 3-year A6111143 study.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Name of medicine, other**

Xalatan

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### **Study drug International non-proprietary name (INN) or common name**

LATANOPROST

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### **Medical condition to be studied**

Glaucoma drug therapy

Ocular hypertension

## Population studied

### **Short description of the study population**

No minimum number of subjects is planned in this study. The number (i.e., 23) is estimated based on the number of subjects enrolled into the A6111143 study (178 subjects) and hypothetical discontinuation rate in the A6111143 (50%),

participation rates in the A6111144 study (50%) and discontinuation rate in the A6111144 studies (50%).

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### **Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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### **Estimated number of subjects**

23

## **Study design details**

### **Outcomes**

Hyperpigmentation changes in the eye(s)

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### **Data analysis plan**

Data analysis will be performed for the entire 10-year follow-up period for all patients enrolled in the A6111144 study. Patient demographics (eg, age and sex) and clinical characteristics (eg, diagnosis of glaucoma) will be summarized for patients in latanoprost treatment group and non topical PGA treatment group. The number and proportion of patients who discontinue participation, and the reasons for discontinuation will be summarized by year for the 10-year period. Incidence number and incidence proportion of hyperpigmentation of the eye will be calculated by study groups as appropriate. Incidence number is the total number of patients that experience at least 1 notable increase of hyperpigmentation of the eye in at least one follow-up visit over 10 years. Incidence proportion is the percentage of patients that experience at least 1

notable increase of hyperpigmentation of the eye in at least one follow-up visit over 10 years. Incidence rate will also be estimated as appropriate.

## Documents

### Study publications

[Younus M, Schachar RA, Zhang M, Sultan MB, Tressler CS, Huang K, Xu W, Klein M,...](#)

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## 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 sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)



**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No