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

Study ID

38741

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Colombia
- ☐ Denmark

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Peru
- [ ] Portugal
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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 (± 2 months) and LSLV is estimated to occur in January 2023 (± 2 months). Submission of the final study report will occur within one year after the LSLV (estimated January 2024 ± 2 months).

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

Prasanna C Ganapathi PrasannaC.Ganapathi@viatris.com

Study contact

PrasannaC.Ganapathi@viatris.com

Primary lead investigator

Arun Kumar

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/02/2014

Actual: 28/02/2014

Study start date

Planned: 11/03/2014

Actual: 11/03/2014

Data analysis start date

Planned: 01/02/2023

Actual: 08/05/2023

Date of interim report, if expected

Planned: 31/07/2019

Actual: 03/07/2019

Date of final study report

Planned: 31/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Viatris Specialty LLC

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 type:

Non-interventional study

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

Medicinal product name, other

Xalatan

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

LATANOPROST

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%).

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)

Estimated number of subjects

23

Study design details

Outcomes

Hyperpigmentation changes in the eye(s)

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,…

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No