The Evaluation of the Safety and Patient Satisfaction with Glash Vista in the Treatment of Patients with Hypotrichosis of the Eyelashes

First published: 08/11/2016

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Study Ongoing

Administrative details

EU PAS number

EUPAS16107

Study ID

27604

DARWIN EU® study

No

Study countries

Japan

Study description

The purpose of this study is to evaluate the safety and patient satisfaction with Glash Vista in the treatment of bypotrichosis of the eyelash through active surveillance under routine clinical practice after the launch of the Glash Vista in Japan. Target Patient PopulationPatients who have been prescribed Glash Vista in select clinical settings and filled at least one prescription for Glash Vista. Sample Size1500 patients with hypotrichosis of the eyelashes who have been prescribed and have used Glash Vista at least once and also have completed at least one follow-up visitStudy Sites The study will be conducted in 75-300 medical institutions, mainly in the departments of dermatology, aesthetic plastic surgery and ophthalmology, recruiting 3-20 patients per institution. Doctors who agree to participate will fill out a registration form for their patients treated with the drug. After the follow-up period, participating doctors will fill out a case report form for each of their enrolled patients (including those who drop out from the study). Follow-upEnrolled patients will be follow-up for one after study enrollment. safety and patient satisfaction data will be collect at 1, 4 and 12 months after study enrollment. Study DurationPatients will be enrolled into the study during the first 2 and half years after study drug launch in Japan. Total study period is 3 and half years. Analysis The analyses will be descriptive in nature, and there are no plans for formal statistical hypothesis testing. Results will be displayed in tabular format (ie, summary statistics, frequency distribution of item responses, and incidence rates with corresponding 95% confidence intervals CI). No imputations for missing data are planned.

Study status

Ongoing

Research institutions and networks

Institutions

Quintiles

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anita Verga

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2014

Actual: 01/12/2014

Study start date

Actual: 24/12/2014

Date of final study report

Planned: 30/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

192024-089 PMS Protocol v2.pdf (244.01 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

192024-089

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

1) Safety of Glash Vista treatment in patient with hypotrichosis of the eyelashes by identifying and evaluating adverse events (AEs) and rates of these events, including serious adverse events (SAEs) and non-serious AEs2) Patient satisfaction with Glash Vista in the treatment of patients with hypotrichosis of the eyelashes by evaluating pre- and post- treatment patient satisfaction surveys

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Glash Vista

Medical condition to be studied

Hypotrichosis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

1.500

Study design details

Outcomes

Incidence of the following:a. Iridal hyperpigmentationb. Enophthalmos (deepened eyelid sulcus)c. Periorbital tissue hyperpigmentationd. Punctate Keratitis, a) Other AEsb) Patient satisfaction

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Data analysis plan

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied. Categorical variables (eg, gender) will be summarized by the number and percentage (%) of patients in each category. For describing the incidence of adverse events, the frequency, cumulative incidence proportion, patient-year incidence rate, and 95%CI for the cumulative incidence measures will be displayed. Unless otherwise specified, the 95% CI of the proportions will be calculated using the exact method, and the 95% CI of the incidence rates will be constructed assuming the frequency of a particular event in a given period of time follows a Poisson distribution.A frequency table by type of adverse event will be prepared. The causal relationship to Glash Vista, outcome and treatment for AE will be described.

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