

# 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

### PURI

<https://redirect.ema.europa.eu/resource/27604>

### 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 hypotrichosis of the eyelash through active surveillance under routine clinical practice after the launch of the Glash Vista in Japan. Target Patient Population Patients who have been prescribed Glash Vista in select clinical settings and filled at least one prescription for Glash Vista. Sample Size 1500 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 visit Study 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-up Enrolled 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 Duration Patients 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.

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### Study status

Ongoing

## Research institution and networks

### Institutions

#### Quintiles

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Institution

## Contact details

### Study institution contact

Anita Verga

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

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### **Study start date**

Actual:  
24/12/2014

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### **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

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**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

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**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 hypotr

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine, other**

Glash Vista

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**Medical condition to be studied**

Hypotrichosis

## Population studied

**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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**Estimated number of subjects**

1500

## Study design details

**Outcomes**

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

### **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

### 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