

# An observational evaluation of the off-label prescribing and safety of glycopyrronium bromide for symptomatic treatment of severe sialorrhoea (drooling) and/or hyperhidrosis (excessive sweating) (Glycopyrronium Bromide)

**First published:** 15/10/2018

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS26094

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### Study ID

27309

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### DARWIN EU® study

No

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### Study countries

## Study description

The proposed study will characterise real-world prescribing of GLY for the symptomatic treatment of severe sialorrhoea and/or excessive sweating. The study will then evaluate safety in patients prescribed GLY for sialorrhoea and/or excessive sweating compared to those not prescribed treatment. Data from this study will provide evidence towards a license evaluation for the use of GLY in the treatment of sialorrhoea and/or excessive sweating in adults in the UK.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Observational & Pragmatic Research Institute Pte (OPRI)

 United Kingdom

**First published:** 06/10/2015

**Last updated:** 19/08/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Contact details

### **Study institution contact**

David Price [dprice@opri.sg](mailto:dprice@opri.sg)

Study contact

[dprice@opri.sg](mailto:dprice@opri.sg)

### **Primary lead investigator**

David Price

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 20/08/2018

Actual: 20/08/2018

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### **Study start date**

Planned: 17/09/2018

Actual: 17/09/2018

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### **Date of final study report**

Planned: 30/11/2018

Actual: 29/10/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Morningside Healthcare

## Regulatory

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

Unknown

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To quantify off-label prescribing of GLY for the symptomatic treatment of sialorrhoea (drooling) and/or excessive sweating. To evaluate adverse events (AE) in patients prescribed GLY for the symptomatic treatment of sialorrhoea (drooling) and/or excessive sweating compared to those not prescribed treatment.

## Study Design

**Non-interventional study design**

Cohort

## Population studied

**Short description of the study population**

Patients prescribed glycopyrronium bromide (GLY) for sialorrhoea and/or excessive sweating were compared to those not prescribed treatment.

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**Age groups**

- 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)
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## Estimated number of subjects

3500

## Study design details

### Data analysis plan

The Chi-squared test or the Fisher's exact test will be used to compare adverse events between the two groups. The total number of AEs will be computed along with the treatment duration, and the incidence rates will be calculated for the two groups and compared. The Poisson regression model would be used to compare the rate of all AE events for the GLY group as compared to the controls.

## 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)

[Electronic healthcare records \(EHR\)](#)

## 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**

Unknown