

# Drug utilisation and incident rates of adverse events in children with sialorrhoea who are treated with glycopyrronium (Glyco Sialorrhoea)

**First published:** 18/07/2022

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS48222

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### Study ID

49596

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

This study will evaluate evidence of medical use of glycopyrronium for sialorrhoea in children with (a) specific focus on drug utilization, including underlying demographics, associated indications or underlying disease conditions, and (b) treatment emergent adverse events in patients started on glycopyrronium. This is a retrospective cohort study focusing on specific evidence on safety, with particular attention on the unknown frequency of cardiovascular events, urinary retention, and respiratory infections that may or may not be associated with glycopyrronium therapy

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**University of East Anglia**

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**Institution**

## Contact details

### **Study institution contact**

Yoon Loke [y.loke@uea.ac.uk](mailto:y.loke@uea.ac.uk)

**Study contact**

[y.loke@uea.ac.uk](mailto:y.loke@uea.ac.uk)

## Primary lead investigator

Yoon Loke

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 28/06/2022

Actual: 15/07/2022

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### Study start date

Planned: 29/07/2022

Actual: 09/08/2022

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### Data analysis start date

Planned: 30/08/2022

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### Date of final study report

Planned: 01/10/2022

Actual: 31/10/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Syri Ltd.

## 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:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Retrospective Cohort study comprising of two components: Descriptive drug utilisation study of children with sialorrhoea who have been prescribed glycopyrronium. Hypothesis generating study regarding frequency or incidence of treatment-emergent adverse events in patients who have been prescribed glycopyrronium, as compared to those who are non users.

## Study Design

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

Cohort

## Study drug and medical condition

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

GLYCOPYRRONIUM BROMIDE

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

Salivary hypersecretion

## Population studied

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

The study participants were sialorrhoea children treated with glycopyrronium bromide identified from the Optimum Patient Care Research Database (OPCRD).

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### **Age groups**

- Children (2 to < 12 years)

- Adolescents (12 to < 18 years)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with sialorrhoea

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### **Estimated number of subjects**

400

## Study design details

### **Outcomes**

Adverse Events in the cardiovascular, respiratory and renal systems in patients with sialorrhoea.

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### **Data analysis plan**

1. As part of the drug utilisation study, we will record baseline demographics and duration of treatment, We will count the number of patient with diagnostic codes for sialorrhoea, use of glycopyrronium, and the number of children with diagnoses of chronic neurological conditions (such as cerebral palsy). 2. We will use Poisson regression to analyse incidence rate of specific adverse events for all glycopyrronium users with sialorrhoea as compared to patients who have not been treated with glycopyrronium. For each particular adverse effect (classified according to major organ systems), we will only consider treatment-emergent adverse events in children who are 'current users' at that point in time. Follow-up time will be based on date of first prescription until 30 days after the last recorded prescription before age of 18 years is attained. We will estimate incidence in the control group based on follow-up time from diagnosis of

sialorrhoea till age of 18 years.

## 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 source(s)

Optimum Patient Care Research Database

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### 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**

No