A study to assess utilisation and safety of Glycopyrronium Bromide 1mg/5ml Oral Solution as licensed for symptomatic treatment of severe sialorrhoea in children and adolescents aged 3 years and older with chronic neurological disorders in the UK

First published: 20/02/2023

Last updated: 05/05/2026

Study Finalised

Administrative details

EU PAS number

EUPAS103644

Study ID

103945

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A prospective cohort study to assess the utilisation and safety of Glycopyrronium Bromide 1mg/5ml oral solution for treatment of severe sialorrhoea in children and adolescents aged 3 years and older with chronic neurological disorders in the UK. Paediatric prescribers/centres will be recruited to the study and children who have been prescribed Glycopyrronium Bromide as advised/prescribed by the recruited paediatricians will be identified over a 30 month recruitment period. Primary and secondary data will be collected on these patients over a 12 month observation period using electronic data capture. Summary descriptive statistics and incident risk/rate estimates for adverse events will be produced. Time to onset of adverse events and follow up consultations will be summarised.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 09/01/2026

Institution | Not-for-profit | ENCePP partner

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/08/2017

Study start date
Actual: 01/04/2022

Data analysis start date
Planned: 29/09/2023

Actual: 02/06/2025

Date of interim report, if expected
Planned: 30/11/2023

Actual: 07/03/2024

Date of final study report
Planned: 04/11/2025

Actual: 08/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Colonis

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

A non-interventional prospective cohort study.

Main study objective:

To assess utilisation and safety of Glycopyrronium Bromide 1mg/5ml Oral Solution as licensed for symptomatic treatment of severe sialorrhoea in children and adolescents aged 3 years and older with chronic neurological disorders in the UK.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

GLYCOPYRRONIUM BROMIDE

Medical condition to be studied

Salivary hypersecretion

Population studied

Short description of the study population

Any patient aged <18 years prescribed Glycopyrronium Bromide 1mg/5ml Oral Solution within six months prior to enrolment, for an indication of sialorrhea, was eligible to participate.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

100

Study design details

Setting

Patients were recruited in secondary care sites across the UK; 14 sites participated.

Outcomes

To describe utilisation of Glycopyrronium Bromide 1mg/5ml Oral Solution in the UK in patients <18 years: 1. To describe off-label use in patients aged below 3 years and/or patients with mild to moderate sialorrhoea 2. To quantify the incidence of patients with the sialorrhoea indication that have a follow up consultation for the medication/indication in secondary and/or primary care, To examine safety in long-term use (as defined by >24 weeks) for the sialorrhoea indication. This will include: 2.1. To examine the incidence of important identified and potential risks within the first 12 months after starting treatment for the sialorrhoea indication

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Data analysis plan

Evaluable cohort demography will be presented using summary descriptive statistics including age and gender, as reported at index date using all available information from electronic data collection forms. Duration of treatment for all patients will be presented using summary descriptive statistics. Use for longer than 24 weeks will be quantified, and adverse events reported after 24 weeks will be summarised.

Summary results

Most patients enrolled in this study were prescribed Glycopyrronium Bromide according to the licensed indication: use in patients three years or older for severe drooling. Nevertheless, offlabel use was observed in approximately one-third of the cohort. Specifically, n<5 patients were prescribed the product under the age of three years, and an additional n<5 patients had a moderate drooling severity. Whilst a high proportion of patients started Glycopyrronium Bromide according to the dosing schedule, patients were also prescribed a dose which fell

between specified Dose levels or less than the recommended Dose level 1 for the patient’s weight. Two-thirds of patients experienced at least one adverse event listed as an important identified or potential risk. Constipation was the

most frequent experienced event, followed by pneumonia. Longer term safety data (>24 weeks) were available for 12 of the 17 patients. Overall, the reported adverse events are consistent with the established safety profile of the product. However, some of these adverse events were serious, either resulting in hospital admission or serious by nature of the adverse event. Deaths were reported during the study period (n<5). The confirmed number of receipt of educational materials was low for HCPs taking part in the study. Due to challenges in patient recruitment leading to a limited sample size, it is not feasible to draw definitive conclusions regarding utilisation, safety, or the effectiveness of the product’s additional risk minimisation measures.

Documents

Abstract of study report

Glycopyrronium Bromide Research Study_Final report abstract.pdf (57.75 KB)

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, Prescription event monitoring, Data from secondary care medical records

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