

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

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Last updated: 23/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS48222

Study ID

49596

DARWIN EU® study

No

Study countries

☐ United Kingdom

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

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

Study contact

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

Study start date

Planned: 29/07/2022

Actual: 09/08/2022

Data analysis start date

Planned: 30/08/2022

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

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

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

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).

Age groups

- Children (2 to < 12 years)

- Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Patients with sialorrhoea

Estimated number of subjects

400

Study design details

Outcomes

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

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 sialorrhea, 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

Data sources (types)

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

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