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: 23/04/2024

Study Ongoing

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

Ongoing

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

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

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

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

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 type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

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

Age groups

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

Estimated number of subjects

100

Study design details

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.

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