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

PURI

https://redirect.ema.europa.eu/resource/27309

EU PAS number

EUPAS26094

Study ID

27309

DARWIN EU® study

No

Study countries

United Kingdom

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.

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

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/08/2018

Actual: 20/08/2018

Study start date

Planned: 17/09/2018

Actual: 17/09/2018

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

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

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 symptomatictreatment of sialorrhoea (drooling) and/or excessive sweating compared to those notprescribed 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.

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)

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 theGLY group as compared to the controls.

Data management

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown