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Analysing the use of glycopyrronium bromide for excessive drooling in young children

Submission date
16/10/2024

Recruitment status
No longer recruiting

Registration date
24/10/2024

Overall study status
Completed

Last Edited
06/11/2024

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study reviews the use of glycopyrronium bromide for the treatment of severe drooling in children below 3 years of age. The purpose of the study is to gather information on its effects and side effects when used in this age group. This information will be obtained from the medical notes of patients already treated with glycopyrronium bromide.

Who can participate?
Children below 3 years of age treated with glycopyrronium bromide who have medical notes at each of the participating sites

What does the study involve?
No participant/patient involvement is required for this study. Researchers will review the medical notes and extract the information required to answer the study questions.

What are the possible benefits and risks of participating?
There will be no direct benefit to those participants who have contributed to the study. The study may benefit children in the future by gathering more efficacy and safety data on the use of glycopyrronium bromide in children under 3 years of age.

As this is a study looking through medical notes only, risks are not anticipated for participants in the study.

Where is the study run from?
The study will be open at five sites throughout the UK - Alder Hey Children's NHS Foundation Trust, Gateshead Health NHS Foundation Trust, Nottingham University Hospitals NHS Trust, Solent NHS Trust and Great Ormond Street Hospital for Children NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
August 2022 to July 2024

Who is funding the study?
Proveca Ltd

Who is the main contact?
Dr Louise Bracken (Chief Investigator) - Lousie.Bracken@alderhey.nhs.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
325926

Protocol serial number
PRO/GLY/005, CPMS 55572

Study information

Scientific Title
Retrospective analysis of real-world evidence on the use of glycopyrronium bromide in children under 3 years of age with sialorrhea

Study objectives
This study is intended to collect retrospective real-world data on the use of glycopyrronium bromide in children under 3 years old, which is not covered by the current license. It is hoped that the data will allow for a retrospective analysis of the safety and efficacy of glycopyrronium bromide in this age group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/05/2023, London - Hampstead Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8009; hampstead.rec@hra.nhs.uk), ref: 23/LO/0427

Study design
Multicentre observational retrospective cohort study

Primary study design
Observational

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Sialorrhoea

Interventions
This is an observational, retrospective, cohort study of enteral glycopyrronium bromide administered for the symptomatic treatment of severe sialorrhoea in patients below 3 years of age, using information already recorded in medical records. Participants who meet the study eligibility criteria will be eligible for inclusion into the study. The study procedures will be limited to the review of the existing medical records of participants from birth to 3 years of age treated with glycopyrronium bromide for sialorrhoea. Potential participants will be identified through a review of the available medical records at participating sites. The national data opt-out will be checked by sites, to ensure no data collected is not from participants who have ‘opted out’. An assessment of compliance with the inclusion/exclusion criteria will be made following subject identification. If all the inclusion criteria are met and the participant lacks all the exclusion criteria, data from the participant will be considered for this retrospective study. If the inclusion criteria are not met, data from the participant will not be collected. Participant data will be extracted from patient’s medical records at each study site and entered into a secure, access-controlled eCRF (REDcap database).

Intervention Type
Other

Primary outcome(s)
There is no primary outcome measure.

The study was not powered for a primary outcome measure - all outcome measures are described in the secondary outcomes

Key secondary outcome(s))
The following secondary outcome measures will be assessed using data collected in the REDcap database at one timepoint:
1. Number of participants with adverse events, where causality has been attributed to glycopyrronium bromide
2. Number of participants with serious adverse events, where causality has been attributed to glycopyrronium bromide
3. Number of participants with glycopyrronium bromide dose reductions due to adverse events
4. Number of participants with glycopyrronium bromide discontinuation due to adverse events
5. A change in a drooling severity scale such as the Drooling Impact Scale (DIS), Modified Teacher's Drooling Scale (mTDS) or other relevant scales. In the absence of any formal rating scale or any other terminology/description/indication that there has been no change, an improvement, or worsening of drooling or sialorrhoea symptoms will be reviewed.
6. Number of participants where glycopyrronium bromide is discontinued due to treatment failure

Completion date
19/07/2024

Eligibility

Key inclusion criteria
1. Aged from birth to less than 30 months of age at the time that glycopyrronium bromide was commenced
2. Treated with glycopyrronium bromide for sialorrhoea (or equivalent terminology) via the enteral route

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 days

Upper age limit
30 months

Sex
All

Total final enrolment
53

Key exclusion criteria
1. Treatment with glycopyrronium bromide for other reasons than sialorrhoea
2. Aged 30 months or over at the time that glycopyrronium bromide was commenced
3. Glycopyrronium bromide given by a route other than the enteral route

Date of first enrolment
25/08/2023

Date of final enrolment
19/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
Gateshead Healthcare NHS Trust
Whinney House
Durham Road
Low Fell
Gateshead
United Kingdom
NE9 5AR

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham

United Kingdom
NG5 1PB

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
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SO19 8BR

Study participating centre
NIHR Great Ormond Street Hospital Clinical Research Facility
Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
Alder Hey Children's Hospital

ROR
https://ror.org/04z61sd03

Funder(s)

Funder type
Industry

Funder Name
Proveca Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the full datasets being commercially sensitive and potentially used to support marketing authorisation applications

IPD sharing plan summary

Not expected to be made available