

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

Submission date 16/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Dr Louise Bracken

ORCID ID

<https://orcid.org/0000-0002-9632-2252>

Contact details

Alder Hey Children's NHS Foundation Trust,
Eaton Road
Liverpool
United Kingdom
L12 2AP
+44 (0)1512525570
louise.bracken@alderhey.nhs.uk

Type(s)

Public, Scientific

Contact name

Dr James Moss

Contact details

Proveca Ltd
WeWork
One St Peter's Square
Manchester
United Kingdom
M2 3DE
+44 (0)1614682627
jamesmoss@proveca.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

325926

ClinicalTrials.gov (NCT)

Nil known

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 sialorrhoea

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
Southampton
United Kingdom
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes