

Trial of Glycopyrronium versus Hyoscine to treat drooling in children - DRI Trial (Drooling Reduction Intervention)

Submission date 22/07/2013	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 22/07/2013	Overall study status Completed	☒ Protocol
Last Edited 15/02/2018	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2013-000863-94

Protocol serial number

14956

Study information

Scientific Title

A single blind study comparing the efficacy of Glycopyrronium and Hyoscine on drooling in children with neurodisability - DRI Trial (Drooling Reduction Intervention)

Acronym

DRI

Study objectives

Drooling is a common problem in children with neurodisabilities such as cerebral palsy or Down Syndrome. Drooling leads to the facial skin becoming sore, frequent changes of clothes, damage to educational equipment, and often social embarrassment for the child and family. There is no evidence about the relative effectiveness of the two medications most commonly used to reduce drooling.

This study aims to identify:

- whether Glycopyrronium or Hyoscine is more effective and at what dose
- side-effects of the medications and how these relate to dose

Over 9 months paediatricians, with special interest in neurodisability working in 15 UK centres, will recruit 90 children from outpatient clinics; these children will not have received any medication for drooling. Children will have a non-progressive neurodisability and be less than 16 years old. They will have no contraindications to the medications. Children will be randomised for treatment and medication will be increased, as tolerated for 4 weeks; this will be under the guidance of the Trial Research Paediatrician, working to the study protocol.

The Trial Outcome Assessor will collect outcome data before the intervention and then at 4, 12 and 52 weeks. Well established scales of the impact of the medication on family and child will be used. Children of sufficient age and ability (identified with help of local paediatrician and the family) will be asked for their own views in an interview.

The results will lead to guidance on: drug doses, intervals for increasing medication, and monitoring of adverse effects. The results have the potential to be adopted immediately because the medications are already in use and surveys of parents and professionals, before the study started, indicates that this trial is needed and the results anticipated with interest.

The overall study duration will be 2 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/NE/0078

Study design

Randomised interventional trial; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions

Primary Intervention, Commencement of Glycopyrronium oral medication or Hyoscine patch.

Secondary intervention, Adjustments to dosing of Glycopyrronium or Hyoscine.

Tertiary Intervention, Appointment to decide on ongoing treatment after 12 weeks.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Glycopyrronium, Hyoscine

Primary outcome(s)

Droling Impact Scale score at 4 weeks

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/09/2014

Eligibility**Key inclusion criteria**

1. Treatment naive children, with nonprogressive neurodisability, who require Glycopyrronium or Hyoscine to reduce drooling
2. No contraindication to either medication
3. Age between 36 months and below 16 years; Target Gender: Male & Female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

36 months

Upper age limit

16 years

Sex

All

Key exclusion criteria

1. Children who have received medical or surgical interventions for drooling
2. Children with medical conditions for which either medication is contraindicated
3. Children whose parents are considered unable to follow the study protocol
4. Parents without mobile or home telephone (required for communication with research registrar and assistant)
5. Parents whose use of English would not allow them to understand the issues in the 6. Consent form or be able to take part in the phone calls with the Trial Research Paediatrician and Trial Outcome Assessor

Date of first enrolment

01/09/2013

Date of final enrolment

30/09/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

4th Floor William Leech Building

Newcastle Upon Tyne

United Kingdom

NE2 4HH

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

Castang Foundation (UK)

Funder Name

Royal College of Paediatrics and Child Health (UK)

Alternative Name(s)

RCPCH Royal College of Paediatrics and Child Health, RCPCH

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

WellChild Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No
Protocol article	protocol	17/02/2014		Yes	No
HRA research summary			28/06/2023	No	No