

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

<b>Submission date</b> 22/07/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/07/2013	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 15/02/2018	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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)**

Drooling 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?
<a href="#">Results article</a>	results	01/04/2018		Yes	No
<a href="#">Protocol article</a>	protocol	17/02/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No