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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Joanne Morrison

Contact details
4th Floor William Leech Building
Framlington Place
Newcastle Upon Tyne
United Kingdom
NE2 4HH
-
joanne.morrison@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number
2013-000863-94

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 that 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Drooling Impact Scale score at 4 weeks

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2013

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

Age group
Child

Lower age limit
36 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

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
England

United Kingdom

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)

Sponsor details
New Victoria Wing
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.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

Funding Body Type

Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
WellChild Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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