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Randomised controlled trial of injection of botulinum toxin into the internal anal sphincter versus control in treatment of chronic idiopathic constipation in children

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
16/04/2018

Condition category
Digestive System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013146059

Study information

Scientific Title
Randomised controlled trial of injection of botulinum toxin into the internal anal sphincter versus control in treatment of chronic idiopathic constipation in children

Study objectives
To investigate the role of needle-free injection of botulinum toxin into external anal sphincter versus injection of the toxin into internal anal sphincter using ordinary needle versus control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Digestive System: Constipation

Interventions
A randomized-controlled trial of botulinum toxin injection versus control in children with chronic idiopathic constipation. The children are randomly allocated by surgeons into two treatment groups after anorectal manometry under ketamine anaesthetic:
Group 1 = injection of botulinum toxin into the internal anal sphincter

Group 2 = the control group who would have the benefits from the hospital admission to have anorectal studies, manual evacuation of stool if necessary, intensification of laxative treatment and toilet training but no botulinum toxin treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Botulinum toxin

Primary outcome measure
Improvement in patients symptom severity score determined by parents completed questionnaire.

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/10/2003

Completion date
01/05/2006

Eligibility

Key inclusion criteria
80 children with idiopathic chronic constipation referred for anorectal manometry and inpatient bowel management programme.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients younger than 3 years old or older than 16 years
2. Severe learning difficulty
3. Evidence of Hirschsprungs disease on anorectal manometry
4. Previous anal surgery

Date of first enrolment
08/10/2003

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK) Own account NHS R&D Support Funding

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