

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

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<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/04/2018	<b>Condition category</b> Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Guy's Hospital

London

United Kingdom

SE1 9RT

# Sponsor information

## Organisation

Department of Health

## 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

## 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes