

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Intrarectal Electromotive Botulinum Toxin Type A Administration In Children With Refractory Constipation

Protocol summary

Study aim

To investigate the effect of electromotive botulinum toxin type A administration in patients with refractory constipation

Design

Sixty patients with refractory constipation were enrolled in the study. Patients were randomly allocated into two equal treatment groups in a balanced randomization study using random block sizes of 4 (ratio; 1:1).

Settings and conduct

Pediatric Urology and Regenerative Medicine Research Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: Refractory constipation according to Rome III criteria, no response to drug therapy Exclusion criteria: Neurological disorder, anatomical disorder, history of anal region or anal sphincter surgery

Intervention groups

In group one, patients underwent electromotive botulinum toxin type A. Catheterization was performed with a 16-Fr electrode catheter, after providing a local intera -anal anesthesia with 2% lidocaine gel. The cuff of the catheter was filled by 2cc saline solution in order to fix the catheter in the rectum. The rectum was then drained and irrigated with 0.9% saline solution until the catheter outflow became clear. The rectum was subsequently filled with 30 cc sterile water and botulinum toxin type A at a dose of 10-15 IU/kg was added to the intra anal solution. Negative electrode as two dispersive electrodes was placed parallel to the midline at the level of the umbilicus or Gluteal region with adequate contact gel. Positive electrode was connected to the intra-anal catheter. The catheter electrodes were attached to a pulsed current generator and the device was adjusted to deliver a current with frequency of 2800 Hz, and amplitude of 10 mA for 20 minutes. Control group: After hospitalization, , the 10-15 IU/kg botulinum toxin type A is injected intra-anal sphincter at 6 and 12 o'clock position in operation room

under anesthesia

Main outcome variables

Defecation frequency per week

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111229008554N4**

Registration date: **2018-05-05, 1397/02/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-05, 1397/02/15**

Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Abdol-mohammad Kajbafzadeh

Name of organization / entity

pediatric urology and reconstructive medicine research center

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 5400

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Intrarectal Electromotive Botulinum Toxin Type A
Administration In Children With Refractory Constipation

Public title
Effect of Electromotive Administration of Botox in
Refractory Constipation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient has constipation according to Rome III
criteria No response to drug therapy No response to
pelvic floor physical therapy
Exclusion criteria:
The patient has neurological disorder The patient has
anatomical disorder The patient has history of anal
region or anal sphincter surgery

Age
From **5 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
The patient with refractory constipation

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly allocated into two equal
treatment groups in a balanced randomization study
using random block sizes of 4 (ratio; 1:1). A computer-
generated list of random numbers was used to allocate
the participants.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessors were blinded. An independent
person records the coded trial data in SPSS. An
independent person analyzes the data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical
Sciences

Street address

Ghods st., Blvd. Keshavarz, Tehran University of
Medical Sciences

City

Tehran

Province

Tehran

Postal code

14194 33151

Approval date

2017-12-12, 1396/09/21

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4232

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipatio

Primary outcomes

1

Description

Defecation frequency per week

Timepoint

At the 1 and 6 months later

Method of measurement

Filling out of bowel diary by parents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients underwent electromotive
botulinum toxin type A. Catheterization was performed
with a 16-Fr electrode catheter, after providing a local
intera -anal anesthesia with 2% lidocaine gel. The cuff of
the catheter was filled by 2cc saline solution in order to
fix the catheter in the rectum. The rectum was then
drained and irrigated with 0.9% saline solution until the
catheter outflow became clear. The rectum was
subsequently filled with 30 cc sterile water and

botulinum toxin A (Dysport, Ipsen, Paris, France) at a dose of 10-15 IU/kg was added to the intraanal solution. Negative electrode as two dispersive electrodes was placed parallel to the midline at the level of the umbilicus or Gluteal region with adequate contact gel. Positive electrode was connected to the intraanal catheter. The catheter electrodes were attached to a pulsed current generator and the device was adjusted to deliver a current with frequency of 2800 Hz, and amplitude of 10 mA for 20 minutes. This procedure was performed without anesthesia on outpatient basis

Category

Treatment - Drugs

2

Description

Control group: After hospitalization, the 10-15 IU/kg botulinum toxin A (dysport) is injected intra-anal sphincter at 6 and 12 o'clock position in operation room under anesthesia, .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Abdol-Mohammad Kajbafzadeh

Street address

No. 62, Dr. Qarib's St, Keshavarz Blvd

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kajbafzd@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadjavad Mohseni

Position

Manager

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Professor
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Subspecialist
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available