

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the outcome of botulinum toxin injection in internal anal sphincter under ultrasound guided with surface probe and without ultrasound in children with constipation

Protocol summary

Study aim

Determining the effect of botox injection in the internal anal sphincter under ultrasound guidance with a surface probe and without ultrasound in children with constipation

Design

The clinical trial, with parallel groups, double-blind, randomized on 40 children

Settings and conduct

In this randomized double-blind clinical trial study, 40 children with constipation referred to Imam Hossein Isfahan Hospital will be included in the study and will be randomly divided into two groups. One group will undergo Botox injection with ultrasound guidance and the other group will undergo Botox injection without ultrasound guidance. Then the improvement of constipation and fecal incontinence of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include children over 3 years old with constipation; failure to respond to treatment; the presence of tuberculous ganglion in the rectal biopsy; no contraindications for botox injection; consent to participate in the study. Exclusion criteria: having constipation caused by Hirschbrung; taking aminoglycoside drugs; penicillamine, quinine, and calcium channel blockers and having neuromuscular junction diseases.

Intervention groups

The intervention group, in this group, botox injection in the sphincter of the patients will be determined by ultrasound with a surface probe in the anus, proximal to the internal sphincter, and 25 units of botulinum toxin type A will be injected in each part. The control group, in this group, without the use of ultrasound and only by touch with the index finger, botox injection will be performed similar to the first group (in terms of amount,

injection location and type of botulinum toxin).

Main outcome variables

Improvement of constipation; fecal incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230704058661N1**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

Masoud Nazem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 1995

Email address

m_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcome of botulinum toxin injection in internal anal sphincter under ultrasound guided with surface probe and without ultrasound in children with constipation

Public title

The outcome of Botox injection in the internal anal sphincter with and without ultrasound guided in children with constipation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children over 3 years old with constipation Failure to respond to medical treatment and lifestyle changes by gastroenterologists The typical Hirschsprung appearance is not seen in the barium enema Presence of tuberculous ganglion in rectal biopsy No contraindications for botox injection Consent to participate in the study

Exclusion criteria:

Constipation caused by Hirschsprung Taking aminoglycoside drugs, penicillamine, quinine, and calcium channel blockers Having neuromuscular junction diseases such as myasthenia gravis

Age

From **3 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 40 eligible children will be randomly selected. For this, the letter A is written on 20 sheets, and the letter B is written on 20 sheets and each of them is placed in an envelope. Each children is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the difference in Botox injection method with and without ultrasound guide, the intervenor is aware of the type of intervention. However, the patient and the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2019-08-06, 1398/05/15

Ethics committee reference number

IR.MUI.MED.REC.1398.249

Health conditions studied**1****Description of health condition studied**

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes**1****Description**

Improvement of constipation

Timepoint

Two weeks, one and three months after botox injection

Method of measurement

Biography of the child's parents

2**Description**

Fecal incontinence

Timepoint

Two weeks, one and three months after botox injection

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, botox injection in the sphincter of patients with ultrasound (ultrasound HONDA ELECTRONICS model HS-2600) with a surface probe (7.5 MHz) in the anus, proximal internal sphincter at 3, 6 and 9 o'clock in the lithotomy position. And 25 units of botulinum toxin type A Dysport will be injected in each part.

Category

Treatment - Drugs

2

Description

Control group, in this group, botox injection will be performed without using sonography and only by touch with the index finger, similar to the first group (in terms of amount, injection location and type of botulinum toxin).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital in Isfahan

Full name of responsible person

Mehrdad Hosseinpour

Street address

Imam Khomeini street

City

Isfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

meh_hosseinpour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Nazem

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Imam Hossein Hospital, Imam Khomeini Street.

City

Isfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

m_nazem@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences
Full name of responsible person
Mehrdad Hosseinpour
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Imam Hossein Hospital, Imam Khomeini Street.
City
Esfahan
Province
Isfahan
Postal code
8195163381
Phone
+98 31 3386 6266
Fax
Email
meh_hosseinpour@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gilda Majdnasiri
Position
Non-faculty specialist doctor
Latest degree

Specialist
Other areas of specialty/work
General Surgery
Street address
Imam Hossein Hospital, Imam Khomeini Street.
City
Isfahan
Province
Isfahan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
majdnasiri@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available