Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the results of botox injection and myctomy in the treatment of children with functional constipation

Protocol summary

Study aim
Comparing the results of botox injection and myctomy in the treatment of children with functional constipation

Design
In this study, a phase three randomized double-blind clinical trial with parallel groups, 64 patients with functional constipation were divided into two groups of 32 people, the first group underwent Botox injection and the second group underwent mycotomy, and the results of treatment between the two groups were compared.

Settings and conduct
This double-blind clinical trial study will be carried out in 1403 in Imam Hossein (AS) hospital in Isfahan. 64 patients are divided into two groups of 32 people, the first group will undergo botox injection and the second group will undergo ahemectomy. Patients and the outcome assessor are unaware of the type of intervention.

Participants/Inclusion and exclusion criteria
In this study, children aged 4 to 16 years old with functional constipation who did not respond to drug treatment and had tuberculous ganglion biopsy and whose parents were willing to participate in the project were included in the study. Also, in the presence of spongy achalasia, the types of hirosprung that have positive radiological findings are not included in the study.

Intervention groups
64 patients are distributed in two groups of 32 people. In the first intervention group, botox is injected in the sphincter area and the second intervention group is subjected to mycotomy.

Main outcome variables
Severe constipation, fecal incontinence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130311012782N59**
Registration date: **2024-02-21, 1402/12/02**
Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**
Update count: **0**

Registration date
2024-02-21, 1402/12/02

Registrant information

Name
Ali Mehrabi kushki

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3629 1510

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-03, 1403/01/15

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the results of botox injection and myctomy in the treatment of children with functional constipation

Public title
The effect of botox and Myctomy on the treatment of functional constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children 4 to 16 years old Suffering from functional constipation Failure to respond to drug treatments Parents' willingness to participate in the study
Exclusion criteria:
Presence of Sphincter achalasia Types of hieroshprung that have positive radiological findings Absence of ganglion in biopsy
Age
From **4 years** old to **16 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients between two groups is done in a simple way. In this way, a number is written on the paper and placed inside the envelope according to the sample size. When the patient enters the operating room, the patient is asked to choose an envelope. Depending on whether the number is even or odd, the patient is placed in one of the two groups of mycotomy or botox injection.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind, and the patients and the person assessing the outcome of the treatment will be unaware of the type of intervention performed.
Placebo
Not 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
Imam Khomini street
City
Isfahan
Province
Isfehan
Postal code
8434193474
Approval date
2020-09-20, 1399/06/30
Ethics committee reference number
IR.MUI.MED.REC.1933.737

Health conditions studied

1

Description of health condition studied
Functional constipation
ICD-10 code
K59.09
ICD-10 code description
Other constipation

Primary outcomes

1

Description
Constipation severity
Timepoint
Before and one year after treatment
Method of measurement
ROME III score

2

Description
Fecal incontinence
Timepoint
Before and one year after treatment
Method of measurement
Rintala score

Secondary outcomes

1

Description
Complications of treatment (abscess, bleeding, pelvic muscle paralysis)
Timepoint
One year after the treatment
Method of measurement
Through examination and history

2

Description
Need for drug therapy
Timepoint
From after the intervention until one year later

Method of measurement
Through examination and history

Intervention groups

1

Description
Intervention group 1: Botox injection group
Category
Treatment - Drugs

2

Description
Intervention group: Myctomy group
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Asadollah Rooshani
Street address
Imam Khomini street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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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
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Asadollah Rooshani
Position
Resident
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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

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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

The plan belongs to the government organization and it is not possible to share it

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