

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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 myctomy, 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 myctomy.

##### 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)

##### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

#### 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

Isfahan

## 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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Isfahan

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**Postal code**

8434193474

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+98 31 3669 2174

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mar0922732@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholamreza Askari

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Hezar Jerib street

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+98 31 3792 3060

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askari@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**

Asadollah Rooshani

**Position**

Resident

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Hoseinpour

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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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Hezarjerib street  
**City**  
Isfahan

## 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