

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of pelvic floor physiotherapy in children with fecal incontinence after surgery for anorectal malformation

#### Protocol summary

##### Study aim

Determining the effect of pelvic floor physiotherapy in children with fecal incontinence after surgery for anorectal malformation compared with conventional medical treatment

##### Design

A randomized clinical trial study with a control group and single blind. The final sample size will be 15 people in each group.

##### Settings and conduct

This study will be performed in the specialized clinic of Tabriz University of Medical Sciences. Thirty children with fecal incontinence after surgery for anorectal malformation aged 4 to 6 years participated in the study with the consent of their parents. This study will be conducted in a single-blind manner and with the blinding of a researcher and statistician.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with fecal incontinence after surgery for anorectal malformations at preschool age (4 to 6 years). These malformations include recto-perinatal fistula and closed anus without fistula in both sexes, which undergo corrective anorectoplasty surgery in three stages before 6 months of age (colostomy at birth and anorectoplasty and then colostomy closure). Exclusion criteria: Children with associated anomalies such as myelomeningocele, congenital hip dislocation, multiple anomalies; Children with learning disabilities.

##### Intervention groups

Intervention group: Pelvic floor physiotherapy including electrical stimulation, biofeedback, and pelvic floor exercises to strengthen the pelvic floor muscles and improve sphincter function. control group: A routine care consists of laxatives and controlling diet and advising to be physically active

##### Main outcome variables

Severity of fecal incontinence and severity of constipation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140811018760N7**

Registration date: **2021-04-15, 1400/01/26**

Registration timing: **prospective**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

##### Registration date

2021-04-15, 1400/01/26

##### Registrant information

##### Name

Fariba Ghaderi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1333 4647

##### Email address

ghaderif@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-11-22, 1400/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of pelvic floor physiotherapy in children with fecal incontinence after surgery for anorectal malformation

## Public title

The effect of pelvic floor physiotherapy in children with fecal incontinence after surgery for anorectal malformation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children with fecal incontinence after surgery for anorectal malformation include recto-perinatal fistula and closed anus without fistula Preschool age (4 to 6 years) undergo corrective anorectoplasty surgery in three stages before 6 months of age (colostomy at birth and anorectoplasty and then colostomy closure). Both sexes

### Exclusion criteria:

Children with associated anomalies such as myelomeningocele, congenital hip dislocation, multiple anomalies Children with learning disabilities

## Age

From **4 years** old to **6 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The participants will be randomly divided into two groups of 15 participants in the intervention and control groups using a random blocking method with block sizes of 4 and 6 and allocation ratio of 1:1. The output will be A or B that each one is representative of one of the groups. To conceal the allocation, the intervention type will be written on a sheet of paper and placed in a opaque envelope with order number on them. Envelopes will be opened in the order as soon as a participant join the study, so the type of group will identified.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This will be a single-blind study, according to the process of interventions, the therapist and the patient can not be blind to the interventions, only the data assessor will be blind to the study groups. The allocation process to the groups will be concealed.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Faculty of Rehabilitation, Daneshgah St., Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167631444

#### Approval date

2021-01-11, 1399/10/22

#### Ethics committee reference number

IR.TBZMED.REC.1399.955

## Health conditions studied

### 1

#### Description of health condition studied

Fecal incontinence

#### ICD-10 code

R15

#### ICD-10 code description

Fecal incontinence

## Primary outcomes

### 1

#### Description

Severity of fecal incontinence

#### Timepoint

At the beginning of the study (before the intervention) and at the end of the intervention

#### Method of measurement

Rintala Questionnaire

### 2

#### Description

Severity of constipation

#### Timepoint

At the beginning of the study (before the intervention) and at the end of the intervention

#### Method of measurement

Pediatric constipation score Questionnaire

## Secondary outcomes

## 1

### Description

Pelvic floor muscles strength

### Timepoint

At the beginning of the study (before the intervention) and at the end of the intervention

### Method of measurement

The strength of pelvic floor muscles will be determined by rectal digital examination and oxford scale.

## Intervention groups

## 1

### Description

Intervention group: Pelvic floor physiotherapy consists of once a week progressive pelvic floor exercises, biofeedback and electrical stimulation at pelvic floor physiotherapy clinic for 12 weeks. Each session will take 40-50 minutes. Exercises will continued every day at home.

### Category

Treatment - Other

## 2

### Description

Control group: A routine care consists of laxatives and controlling diet and advising to be physically active

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Pelvic floor physiotherapy clinic - Tabriz University of Medical Sciences

#### Full name of responsible person

Fariba Ghaderi

#### Street address

Pelvic floor physiotherapy clinic - Tabriz University of Medical Sciences

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5167654455

#### Phone

+98 41 3329 9799

#### Email

ghaderif@tbzmed.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

### Name of organization / entity

Tabriz University of Medical Sciences

### Full name of responsible person

Mohammad Samiei

### Street address

Tabriz, University street, Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences

### City

Tabriz

### Province

East Azarbaijan

### Postal code

5167631444

### Phone

+98 41 3334 5121

### Fax

+98 41 3334 5121

### Email

ghaderif@tbzmed.ac.ir

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Fariba Ghaderi

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiotherapy

#### Street address

Faculty of Rehabilitation, Daneshgah St., Tabriz

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+98 41 3334 5121

**Email**

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## Person responsible for scientific inquiries

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Professor

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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**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

The study protocol, statistical analysis data and informed consent form will be available if requested by another researcher via email.

**When the data will become available and for how long**

6 months after the publication of the article

**To whom data/document is available**

For researchers working in scientific and academic institutions

**Under which criteria data/document could be used**

At the request of the journals or the reviewers of the journals

**From where data/document is obtainable**

By email and by providing documentation for authentication through the project manager Dr. Fariba Ghaderi ghaderimailbox@gmail.com or ghaderif@gmail.com

**What processes are involved for a request to access data/document**

Send request via email and authentication documents

**Comments**