

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Determination of the effects of toilet training in the treatment of functional constipation in children

Protocol summary

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Summary

This study compares the effects drug therapy and behavioral therapy techniques such as toilet training to the children suffering from functional constipation. In this study, 100 children with the diagnosis of functional constipation, referred to Gastroenterology Clinic of Aliasghar Hospital will be assigned to receive drug treatment (Lactulose 1 gram/kilogram and a teaspoonful senagol) or behavioral therapy (sitting for 10 to 15 minutes in the toilet after each meal). Total suppository use, use of laxatives, Soiling underwear, the rate of painful defecation, going to the toilet and complications during treatment will be recorded and compared between groups.

Recruitment status

Recruitment complete

Funding source

Ali asghar hospital, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2010-06-24, 1389/04/03

Expected recruitment end date

2011-07-09, 1390/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012275479N1**

Registration date: **2011-02-21, 1389/12/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-21, 1389/12/02

Registrant information

Name

Tahereh Parvini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 2041

Email address

Scientific title

Determination of the effects of toilet training in the treatment of functional constipation in children

Public title

Determination of the effects of toilet training in the treatment of functional constipation in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children between 3- 12 Exclusion criteria: age less than 3 and more than 12, any causes of disability, physical or mental, any systemic diseases

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences and Health Services
Street address
Hemmat Highway, Next to the Milad Tower
City
Tehran
Postal code
Approval date
2010-10-24, 1389/08/02
Ethics committee reference number
896/1

Health conditions studied

1

Description of health condition studied
Functional constipation
ICD-10 code
K59.0
ICD-10 code description
change in bowel habit NOS

Primary outcomes

1

Description
Go to the toilet
Timepoint
daily
Method of measurement
Questionnaire

2

Description
The rate of painful defecation
Timepoint

daily
Method of measurement
Questionnaire

3

Description
Underwear soiling
Timepoint
daily
Method of measurement
Questionnaire

4

Description
Use of laxatives
Timepoint
daily
Method of measurement
Questionnaire

5

Description
Total suppository use
Timepoint
daily
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Senagol 1 gram per KG Lactolose 1 teaspoonful for four months
Category
Treatment - Drugs

2

Description
Behavioral therapy including: 10 to 15 minutes remaining in toilet for four months
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali asghar hospital
Full name of responsible person
Dr. Nakhaei
Street address

Zafar st., North modarres highway, Tehran

City

Tehran

Tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Otukesh

Street address

North modarres highway - Ali asghar hospital

City

Tehran

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 and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Tahereh Parvini

Position

Pediatric Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shahrbanoo Nakhaee

Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty