

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative efficacy of inferential electrical stimulation and functional electrical stimulation on functional constipation in children

Protocol summary

Study aim

To compare efficacy of inferential and functional electrical stimulation on functional constipation in children

Design

Pragmatic, community based, parallel group, double blind, randomized controlled trial

Settings and conduct

Fifty patients were randomly allocated into two equal treatment groups in a balanced randomization study using random block sizes of 4 (ratio; 1:1). A computer-generated list of random numbers was used to allocate the participants. Group 1 (n=25) underwent PFM exercises plus IF electrical stimulation on abdomen while the group 2 (n=25) received PFM exercises plus functional electrical stimulation on beside of anus. All patients/parents and physicians were blind to the group enrollment. The physiotherapist was not blind to the treatment interventions, although the outcome assessors were blinded. All patients underwent 10 sessions treatment program twice a week.

Participants/Inclusion and exclusion criteria

Defecation frequency of less than 3 times per week, passing of hard stool, episodes of fecal soiling, abnormal stool form, age of 4 years or more

Intervention groups

For both groups 10 sessions treatment program, twice a week were performed. Group 1 = Inferential electrical stimulation (on the abdomen for 20 minutes). A frequency of 5-25 Hz for duration of 250 μ s, and a repeat time of 6 s with adjustable amplitude (0-50 mA). Two electrodes, one from each channel, were placed on the skin of anterior abdominal wall below the costal margin bilaterally and two other electrodes from each channel were crossly placed on the back between T12 and L4 on either sides of the patients. Group 2 = Functional electrical stimulation (beside of anus for 20 minutes). A frequency of 40 Hz, duration of 250 μ s, hold and rest time of 3 seconds with adjustable amplitude (range

0-100 mA).

Main outcome variables

An increase in defecation frequency of 2 times per week more than baseline

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140527017876N5**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Lida Sharifi Rad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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l-sharifirad@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative efficacy of inferential electrical stimulation and functional electrical stimulation on functional constipation in children

Public title
Effect of electrical stimulation on constipation in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Defecation frequency of less than 3 times per week Age of 4 years or older Abnormal stool form Confirmed constipation according to the Rome IV criteria
Exclusion criteria:
 Neuropathic bowel dysfunction ; Inflammatory disease Metabolic disease

Age
From **4 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly allocated into two equal treatment groups in a balanced randomization study using random block sizes of 4 (ratio; 1:1). A computer-generated list of random numbers was used to allocate the participants.

Blinding (investigator's opinion)
Double blinded

Blinding description
All patients/parents and physicians were blind to the group enrollment . The physiotherapist was not blind to the treatment interventions, although the outcome assessors were blinded. An independent person recorded the coded trial data in SPSS

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committe of Children's Medical Center

Street address

No. 62, Dr. Qarib St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

14194 33151

Approval date

2022-04-21, 1401/02/01

Ethics committee reference number

IR.TUMS.CHMC.REC.1401.012

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Defecation frequency per week

Timepoint

Before treatment, at the end of treatment sessions and 6 months later

Method of measurement

Bowel diary

Secondary outcomes

1

Description

Fecal soiling episodes

Timepoint

Before treatment, at the end of treatment sessions and 6 months later

Method of measurement

Bowel diary

Intervention groups

1

Description

Intervention group:For both groups 10 sessions

treatment program, twice a week were performed. Group 1 = Inferential electrical stimulation (on the abdomen for 20 minutes). A frequency of 5-25 Hz for duration of 250 μ s, and a repeat time of 6 s with adjustable amplitude (0-50 mA). Two electrodes, one from each channel, were placed on the skin of anterior abdominal wall bellow the costal margin bilaterally and two other electrodes from each channel were crossly placed on the back between T12 and L4 on either sides of the patients. Group 2 = Functional electrical stimulation (beside of anus for 20 minutes).A frequency of 40 Hz, duration of 250 μ s, hold and rest time of 3 seconds with adjustable amplitude (range 0-100 mA)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Sixth floor, Ghods st, Vice Chancellor for Research of
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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

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

Tehran University of Medical Sciences

Full name of responsible person

Lida Sharifi Rad

Position

Physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

Physiotherapist

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Final report

When the data will become available and for how long

After publication

To whom data/document is available

Researchers

Under which criteria data/document could be used

For performance of other study

From where data/document is obtainable

Pediatric Gastroenterology and Hepatology Research Center

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

A request form Institute to Pediatric Gastroenterology and Hepatology Research Center

Comments