

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effects of interferential electrical stimulation and functional pelvic floor muscle exercises on functional constipation and painful defecation in children

Protocol summary

Summary

Objectives: To evaluate the effects of interferential electrical stimulation and pelvic floor muscle exercises on functional constipation and painful defecation in children **Design:** A double blind clinical trial study. **Setting and conduct:** Ninety children with functional constipation were enrolled in the study and were randomly divided into two treatment groups. Participants including major eligibility criteria: Inclusion criteria including: age more than 4 years old, abnormal stool form and defecation frequency less than 3 times per week. Exclusion criteria including: neuropathic bowel dysfunction, inflammatory and metabolic disease. **Intervention:** Case group (n=45 children) underwent transabdominal interferential electrical stimulation, behavioral therapy and pelvic floor muscle exercises for 10 sessions, 2 times per week. Control group (n=45 children) underwent sham transabdominal electrical stimulation, behavioral therapy and pelvic floor muscle exercises for 10 sessions, 2 times per week. All patients were evaluated by a complete bowel diary with data on the frequency of defecation per week, stool form and the number of fecal soiling episodes, a constipation score and a visual pain score before, after treatment and 6 months later. Then outcomes were compared between two groups. Main outcome measures (variables): Primary outcome is an increase in defecation frequency of 2 times per week more than baseline. Secondary outcomes are presence or absence of fecal soiling, stool form and pain score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030617876N2**
Registration date: **2017-04-07, 1396/01/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-07, 1396/01/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of interferential electrical stimulation and functional pelvic floor muscle exercises on functional constipation and painful defecation in children

Public title

Effects of interferential electrical stimulation and pelvic floor muscle exercises on functional constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 4 years old; abnormal stool form; painful defecation; defecation frequency less than 3 times per week
Exclusion criteria: Neuropathic bowel dysfunction; inflammatory disease; metabolic disease

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Qhods St, Keshavarz Bolv.

City

Tehran

Postal code

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

IR.TUMS.REC.1395.2889

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

At the end of treatment sessions and 6 months later

Method of measurement

Filling out bowel habit diary by parents

Secondary outcomes

1

Description

Fecal soiling episodes

Timepoint

At the end of treatment sessions and 6 months later

Method of measurement

Bowel habit diary

2

Description

Stool form

Timepoint

At the end of treatment sessions and 6 months later

Method of measurement

Bristol Stool Form

3

Description

Pain

Timepoint

At the end of treatment sessions and 6 months later

Method of measurement

A visual pain score

Intervention groups

1

Description

Children in case group underwent 10 therapeutic sessions , 2 times per week. In each session, patients underwent functional pelvic floor muscle exercises, toilet training and IF electrical stimulation. IF therapy was applied for 20 minutes, frequency of 5-25 Hz for a duration of 250 μ s, and a repeat time of 6 s with adjustable amplitude (0-50 mA). Two rectangular (2.5×3.5 cm) 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. The current from each channel crossed inside the abdomen. The intensity was increased until the patient declared a strong but comfortable level of sensory awareness with no muscle contractions. Maximum current intensity was below the pain threshold and was tolerated well by the patients.

Category

Rehabilitation

2**Description**

Children in control group underwent 10 therapeutic sessions, 2 times per week. In each session, patients underwent functional pelvic floor muscle exercises, toilet training and sham IF electrical stimulation. Sham IF therapy was applied for 20 minutes. Two rectangular (2.5×3.5 cm) 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. The intensity was not increased.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Physical Therapy, Children Hospital Medical Center

Full name of responsible person

Lida Sharifi Rad

Street address**City**

Tehran

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

Vice-Chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Younesian

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6th floor, Central of Organization, Ghods St, Keshavarz Blvd.

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Grant name**Grant code / Reference number**

30373

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

Yes

Title of funding source

Vice-Chancellor for Research of Tehran University of Medical Sciences

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

Full name of responsible person

Lida Sharifi Rad

Position

Physiotherapist/Head of Physical Therapy Department

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Position

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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