Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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

Name

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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 episods
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 μs, 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 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.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 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. 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 Bolv.

City

Tehran

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

Other areas of specialty/work

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Other areas of specialty/work

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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