

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effectiveness of treatment with transcutaneous functional electrical stimulation and biofeedback in improving of functional non-retentive fecal incontinence in children

Protocol summary

Study aim

To evaluate the effects of transcutaneous functional electrical stimulation with or without biofeedback on functional non-retentive fecal incontinence in children.

Design

Forty five children with functional non-retentive fecal incontinence were enrolled in the study. Patients were randomly allocated into three equal treatment groups in a balanced randomization study using random block sizes of 4 (ratio; 1:1).

Settings and conduct

This study was performed in the Children's Medical Center , Tehran University of Medical Sciences, Tehran, Iran

Participants/Inclusion and exclusion criteria

Participants including major eligibility criteria: Inclusion criteria including: age 5 years old or more, at least once fecal incontinence episodes per week . Exclusion criteria including: neuropathic bowel dysfunction, inflammatory bowel disease and metabolic disease.

Intervention groups

Intervention: Group 1 comprised of 15 patients who underwent transcutaneous functional electrical stimulation (20 minutes on the anal region) and pelvic floor muscles training by biofeedback for 10 treatment sessions. Group 2 comprised of 15 patients who underwent transcutaneous functional electrical stimulation (20 minutes on the anal region) for 10 treatment sessions. Control group including 15 patients who underwent only medical treatment. All patients (cases and controls) were evaluated at the end of treatment sessions and 6 months later by bowel habit diary and then results were compared between groups.

Main outcome variables

Primary outcome is a decrease in fecal soiling episodes per week . Secondary outcomes are changing in defecation frequency per week, stool form and pain

score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140527017876N4**

Registration date: **2018-03-16, 1396/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-16, 1396/12/25**

Update count: **0**

Registration date

2018-03-16, 1396/12/25

Registrant information

Name

Lida Sharifi Rad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6147 2090

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of treatment with transcutaneous functional electrical stimulation and biofeedback in improving of functional non-retentive fecal incontinence in children

Public title
Effects of transcutaneous functional electrical stimulation with or without biofeedback on functional non-retentive fecal incontinence in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age of 5 years old or more Presence of fecal incontinence episode at least once a week No history of previous constipation
Exclusion criteria:
 Neuropathic bowel dysfunction Inflammatory bowel disease Metabolic disease

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

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

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods st., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

14194 33151

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.TUMS.CHMC.REC.1396.4427

Health conditions studied

1

Description of health condition studied

Fecal incontinence

ICD-10 code

F98.1

ICD-10 code description

Fecal incontinence

Primary outcomes

1

Description

Number of fecal incontinence episodes

Timepoint

At the end of treatment sessions and 6 months later

Method of measurement

Filling out of bowel habit diary by parents

Secondary outcomes

1

Description

Defecation frequency per week

Timepoint

At the end of treatment sessions and 6 months later

Method of measurement

Filling out a bowel habit diary by parents

2

Description

Stool form

Timepoint

At the end of treatment sessions and 6 months later

Method of measurement

Filling out a bowel habit diary by parents

3

Description

Pain
Timepoint
At the end of treatment sessions and 6 months later
Method of measurement
Pain scoring system

Intervention groups

1

Description

Children in group 1 (n=15) underwent 10 treatment sessions, two times per week. In each session, patients underwent pelvic floor muscle exercise by biofeedback for 10 minutes and transcutaneous functional electrical stimulation of anal region. Functional electrical stimulation was performed for 20 minutes with frequency of 40 Hz and hold and rest time of 3 seconds.

Category

Rehabilitation

2

Description

Children in group 2 (n=15) underwent 10 treatment sessions, two times per week. In each session, patients underwent transcutaneous functional electrical stimulation of anal region. Functional electrical stimulation was performed for 20 minutes with frequency of 40 Hz and hold and rest time of 3 seconds.

Category

Rehabilitation

3

Description

Control group: Patients in control group (n=15) only underwent medical treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Lida Sharifi Rad

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No. 62, Dr. Qarib St, Keshavarz Blvd

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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. Mohammad-Ali Sahraeian

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

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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

Vice-Chancellor for Research of 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

Seyedeh-Sanam Ladi-Seyedian

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Lida Sharifi Rad
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Master
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Person responsible for updating data

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Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Unrecognized individual data of patients

When the data will become available and for how long

After ending of the study

To whom data/document is available

For staff in academic institutions

Under which criteria data/document could be used

In comparison with other therapeutic methods

From where data/document is obtainable

No. 62, Dr. Qarib St, Keshavarz Blvd , Children's Medical Center, Tehran,Iran Lida Sharifi Rad E-mail : l-sharifirad@farabi.tums.ac.ir Telephone:982161472090

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

The application will be sent to the project manager through the Research Vice-Chancellor of the Tehran University of Medical Sciences

Comments