Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Posterior Tibial Nerve Electrical Stimulation with Conventional Treatments on Improving the Control of Functional Retentive Fecal Incontinence in Children

Protocol summary

Study aim
To determine and compare the effect of posterior tibial nerve electrical stimulation with conventional treatments on improving the control of functional retentive fecal incontinence in children

Design
Two parallel group, Simple Randomized, Not blinded clinical trial, 30 patients

Settings and conduct
This study will be conducted voluntarily in Zahedan, at the Physiotherapy Clinic of Khatam Hospital, on children with retentive fecal incontinence. Patients will be randomly assigned to one of the routine treatment group or the posterior tibial nerve stimulation group. No blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 4 years; having at least two of the Rome IV criteria; receiving pharmacological treatment and dietary therapy for at least 3 months. Exclusion criteria: Patient's unwillingness to receive treatment, Having organic diseases, Having a history of intestinal surgery, Having urinary incontinence concomitant with fecal incontinence.

Intervention groups
Control group: routine treatment, including a daily bowel evacuation program, pelvic floor muscle exercises, diaphragmatic breathing exercises, and dietary management; Intervention group: Posterior tibial nerve stimulation (PTNS) in addition to the routine treatment

Main outcome variables
Severity of fecal incontinence; Resting anal sphincter pressure; Maximum anal sphincter squeeze pressure; First rectal sensation; First urge to defecate; Strong urge to defecate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180714040466N10**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **prospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

Registration date
2026-07-09, 1405/04/18

Registrant information

Name
Fateme Ghiasi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 54 3341 6708

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2027-05-22, 1406/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effect of Posterior Tibial Nerve Electrical Stimulation with Conventional Treatments on Improving the Control of Functional Retentive Fecal Incontinence in Children

Public title
The effect of electrical stimulation on fecal incontinence in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 4 years Having at least two of the Rome IV Criteria Having been Under Drug Therapy and a Dietary Regimen for at least 3 months

Exclusion criteria:
Patient's unwillingness to continue participation Having any Organic Disease Having a history of Intestinal Surgery Having Urinary Incontinence Concomitant with Fecal Incontinence

Age
From **4 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization as follows: Based on the number of patients in each group, the particular sort of treatment (the conventional treatment group and the posterior tibial nerve electrical stimulation group) is written on a piece of paper. Each paper is placed in a sealed envelope. One envelope will be chosen randomly by the therapist at the first session of the patient treatment and the patient's treatment technique is selected based on that. If any of the patients is omitted from the study, one envelope related to the excluded patient treatment group will be replaced and they will mixed again.

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
Ethics committee of Zahedan University of Medical Sciences

Street address
Dr. Hesabi Square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2026-05-04, 1405/02/14

Ethics committee reference number
IR.ZAUMS.REC.1405.038

Health conditions studied

1

Description of health condition studied
Functional Retentive Fecal Incontinence

ICD-10 code
R15

ICD-10 code description
Fecal incontinence

Primary outcomes

1

Description
Intensity of fecal incontinence

Timepoint
Before and after the intervention

Method of measurement
Rintala questionnaire

2

Description
Anal sphincter resting pressure

Timepoint
Before and after the intervention

Method of measurement
The pressure biofeedback

3

Description
Maximum anal sphincter squeeze pressure

Timepoint
Before and after the intervention

Method of measurement
The pressure biofeedback

4

Description
First rectal sensation

Timepoint
Before and after the intervention
Method of measurement
The pressure biofeedback

5

Description
First urge of defecate
Timepoint
Before and after the intervention
Method of measurement
The pressure biofeedback

6

Description
Strong urge to defecate
Timepoint
Before and after the intervention
Method of measurement
The pressure biofeedback

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the posterior tibial nerve stimulation group, patients will receive treatment three times per week for 8 weeks, for a total of 24 sessions. The procedure is performed with the patient lying in the supine position. The positive electrode is placed 1.5 inches above the medial malleolus, and the negative electrode is placed below the same malleolus. The current intensity is increased until flexion of the great toe and abduction of the other toes are observed, then reduced to a level at which the patient experiences only tingling or pins-and-needles sensation. Each treatment session lasts 20 minutes. Diaphragmatic breathing exercises, a daily bowel evacuation program, and adherence to a high-fiber diet will also be taught to the patients.
Category
Rehabilitation

2

Description
Control group: Patients in the routine treatment group will receive diaphragmatic breathing exercises, a daily bowel evacuation program, and adherence to a high-fiber diet three times per week for 8 weeks, for a total of 24 sessions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al-Anbia Hospital
Full name of responsible person
Haniye Shoorooei
Street address
Khatam Ai-Anbia Hosp, Jame jam Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Fateme Ghiasi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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