Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of biofeedback, biofeedback plus fiber laxative, and biofeedback plus osmotic laxative for treatment of constipation in patients with pelvic floor dyssynergia

Protocol summary

Study aim

Evaluating the effect of biofeedback in combination with laxatives in patients with constipation due to pelvic floor dyssynergia.

Design

In this single-blinded clinical trial, 88 patients with dyssynergic constipation were randomly divided into 3 groups. After obtaining and confirming their consent, the treatment with "exclusively biofeedback" , or "Biofeedback + psyllium" or biofeedback + polyethylene glycol "were administered for 2 to 3 weeks. All treatments for patients in all three groups were eligible and no intervention beyond treatment protocols. Also, all the research costs came from research project resources, and no additional costs for the clinical evaluations and expert visits were charged.

Settings and conduct

This study was performed on patients with dyssynergic constipation who referred to gastrointestinal ward of Taleghani hospital during the years 2018 to 2019.

Participants/Inclusion and exclusion criteria

Patients who had history or signs of constipation due to dyssynergia confirmed by anorectal manometery, were included. Patients who had constipation due to secondary causes such as using opioids, endocrine diseases, neurologic diseases, history of surgery, etc, were excluded.

Intervention groups

1.The first group were treated with the routine biofeedback method 2. The second group were treated with biofeedback plus fiber laxative (psyllium) 3. The third group were treated with biofeedback plus osmotic laxative (polyethylene glycol)

Main outcome variables

Medication use for evacuation; difficulty to evacuate; digitation to evacuate; return to toilet to evacuate; feeling of incomplete evacuation; straining to evacuate; time needed for evacuation; life style change; rectal bleeding; well being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045274N1**
Registration date: **2020-01-11, 1398/10/21**
Registration timing: **retrospective**

Last update: **2020-01-11, 1398/10/21**
Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Mohammad Sadegh Jamshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2206 0674

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-12-22, 1398/10/01

Scientific title

Comparison of biofeedback, biofeedback plus fiber laxative, and biofeedback plus osmotic laxative for treatment of constipation in patients with pelvic floor dyssynergia

Public title

Effect of biofeedback, psyllium and polyethylene glycol in treating constipation due to dyssynergia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who had history or signs of constipation due to dyssynergia which were confirmed by anorectal maometery

Exclusion criteria:

Patients who had constipation due to secondary causes such as using opioids, endocrine diseases, neurologic diseases, history of surgery, etc.

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **105**

Actual sample size reached: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study we used simple randomized allocation with random number table. All patients had equal chance of being placed in each group.The randomization unit was individualized and the random sequence was based on a random number table.Color, odor, drug form and biofeedback exercise were similar in all groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

n this single blinded study, all participants completed a written informed consent in one of the study groups and in order to avoid prejudice, the subjects were attempted to be as similar in shape, color and smell as possible.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti university of medical sciences

Street address

No. 45, West 18th Ave., Allame Shomali Blvd., Saadatabad

City

Tehran

Province

Tehran

Postal code

1997988435

Approval date

2018-05-05, 1397/02/15

Ethics committee reference number

IR.SBMU.MSP.REC.1398.063

Health conditions studied

1

Description of health condition studied

Constipation due to pelvic floor dyssynergia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

wellbeing by patient

Timepoint

in the beginning of study and three weeks after treatment

Method of measurement

asking the patient

2

Description

medication use to evacuation

Timepoint

in the beginning of study and three weeks after treatment

Method of measurement

asking the patient

3

Description

Digitation to evacuate

Timepoint

in the beginning of study and three weeks after treatment

Method of measurement

asking the patient

4

Description
difficulties to evacuate
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

5

Description
return to toilet to evacuate
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

6

Description
feeling of incomplete evacuation
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

7

Description
straining to evacuate
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

8

Description
time needed to evacuate
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

9

Description
life style alteration
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

10

Description
rectal bleeding
Timepoint
in the beginning of study and three weeks after treatment
Method of measurement
asking the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First group: Patients who are assigned to do biofeedback exercises and also receive 15 grams of psyllium powder twice daily for three weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Second group:Patients who are assigned to do biofeedback exercises and also receive 10 grams of polethylene glycol twice daily for three weeks.
Category
Treatment - Drugs

3

Description
Control group:Patients who are assigned to do biofeedback exercises. Each patient receives one session of education which takes 1.5 hours. They will be taught relaxation of anal sphincter, better sensation of defecation and rectoanal coordination by rectal probe.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Research institute for gastroenterology and liver disease, Taleghani hospital
Full name of responsible person
Hamaid asadzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Habib Malekpour
Position
associate professor
Latest degree
Subspecialist
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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data could be shared after the patients are unidentified.

When the data will become available and for how long

Accessing the information will be 6 months after publishing the data.

To whom data/document is available

The data will be available to all researchers working in scientific and academic institutes.

Under which criteria data/document could be used

The data will only be accessible by academic researchers for use in accredited scientific centers.

From where data/document is obtainable

Dr. Mohammad Sadegh Jamashidi: sadegh.jamshidi@yahoo.com mobile number: 00989123447508

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

The applicant must provide complete information about the field of work, specialty, academic record, email, address and phone number.

Comments