

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigating the effect of biofeedback therapy compared to standard treatment on MR defecography indicators in patients with obstructive excretory syndrome.

Protocol summary

Study aim

Comparison the effect of biofeedback therapy versus standard treatment on Magnetic Resonance(MR)defecography indicators in patients with chronic constipation disorders.

Design

This study is a clinical trial with an intervention and control group conducted in a parallel and double-blind manner. The method of blinding will be in such a way that the subjects and the outcome evaluator will be unaware of the allocation of people to the intervention and control groups. Sample size There will be 14 people in each group and a total of 28 people. For randomization, the block randomization method is used.

Settings and conduct

This study conducted in a parallel and double-blind manner at Imam Khomeini Hospital. The method of blinding will be in such a way that the subjects and the outcome evaluator will be unaware of the allocation of people to the intervention and control groups.

Participants/Inclusion and exclusion criteria

All patients aged 18 to 65 with chronic constipation who have been diagnosed with Obstructive Defecation Syndrome (ODS) based on history, clinical examination and colon transit test will be included in the study. Pregnant and lactating people, and people with a history of substance abuse will not be included in the study.

Intervention groups

Intervention group: It includes people who underwent MR defecography and will be prescribed standard treatment along with biofeedback at the same time. Control group: includes people who will be prescribed standard treatment including high-fiber diet, elimination training and laxative use

Main outcome variables

MR defecography indices before and after biofeedback

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056618N1**

Registration date: **2022-12-14, 1401/09/23**

Registration timing: **prospective**

Last update: **2022-12-14, 1401/09/23**

Update count: **0**

Registration date

2022-12-14, 1401/09/23

Registrant information

Name

Dorsa Hadavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 0000

Email address

yousefkhani1984@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of biofeedback therapy compared to standard treatment on MR defecography indicators in patients with obstructive excretory syndrome.

Public title

Investigating the effect of biofeedback therapy on MR defecography indicators

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from chronic constipation based on history, clinical examinations and colon transit test and confirming the diagnosis of Obstructive Excretion Syndrome (ODS)

Exclusion criteria:

Psychiatric disorders pregnancy breastfeeding Substance abuse

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, 4 blocks of 4 were prepared in Excel software as (AA, BB), (BB, AA), (AB, BA), (BA, AB), (AB, AB), (BA, BA) and Then these blocks will be sorted from one to four. A was for the treatment or intervention group and B was for the control group. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, the eligible people will be assigned to treatment or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, so that the evaluator and the subject are not aware of the status of assigning people to the study groups. For the study subjects, before the random assignment, it is explained how the work process is.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Imam Khomeini Hospital Complex - Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, at the end of Keshavarz Boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.206

Health conditions studied

1

Description of health condition studied

Obstructive Defecation syndrome

ICD-10 code

K59.02

ICD-10 code description

Outlet dysfunction constipation

Primary outcomes

1

Description

MR defecography indicators in patients with obstructive syndrome

Timepoint

The examination of MR defecography indicators will be at the end of the third week after entering the study.

Method of measurement

Measurement and comparison of the results of the intervention will be done using MRI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It will include people who will be given standard treatment including high-fiber diet, training on bowel movement and laxative use along with biofeedback. Before doing biofeedback, it is necessary for the patient to have full knowledge of the functioning

mechanism of the human body and know anorectal anatomy. The examination of the rectal bag is performed on the patient so that the patient gets familiar with the concept of contraction and expansion of the anal sphincter. The training method is side lying, which means that the patient is shown how the anal sphincter works with a bile duct pressure measurement catheter that enters the anal-rectum canal. With the doctor's explanation and guidance, the patient will be able to distinguish abnormal from normal images in this test and can perform the necessary procedures to increase intra-abdominal pressure and systolic pressure at the same time as the anal sphincter relaxes and repeat. The treatment protocol consists of 3 sessions per week and each session lasts for an hour, and each course consists of 8 sessions and will be accompanied by sessions to strengthen autonomous function at home.

Category

Treatment - Other

2

Description

Control group: The patients with diagnosis of Obstructive Defecation Syndrome(ODS) in Imam Khomeini Hospital who are waiting for biofeedback therapy and only receive standard constipation treatment including high fiber diet and using laxatives. These patients undergo MR defecography before and after standard treatment protocol.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dorsa Hadavi

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, at the end of Keshavarz Boulevard, Tehran

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hadavidorsa@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbar Fotouhi

Street address

Research and Technology Vice-Chancellor, 6th corner of Quds St, Organization of the University, Keshavarz Blvd

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Dorsa Hadavi

Position

Radiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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0098 21 61190

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dorsa Hadavi

Position

Radiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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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

Not applicable

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

The data file of the participants, the study protocol, the informed consent form and the clinical study report will be provided to the interested researchers in compliance with the ethical standards, including non-identification of the patients and other such matters.

When the data will become available and for how long

The data access period will start after the publication of the research articles

To whom data/document is available

All researchers interested in working in this field

Under which criteria data/document could be used

The data of the study will be made available to interested parties for the purpose of secondary analysis or other relevant research purposes while maintaining the confidentiality of the participants.

From where data/document is obtainable

To receive data, applicants can write to the email address hadavidorsa@gmail.com

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

After the correspondence by the applicants in order to receive the data of the study, after the necessary checks, the data will be provided to them within a week.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dorsa Hadavi

Position

Radiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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