

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of pelvic motion in patients with chronic constipation due to dyssynergic defecation after biofeedback therapy by MR defecography

Protocol summary

Summary

Objective- We want to compare the effects of Biofeedback Therapy, on pelvic floor motion indices ie., angle change and vertical motion and also Quality of Life and depression, with Standard Therapy in patients with dyssynergic defecation. Specifically we want to study whether MR defecography enable to show the differences between the dynamic indices of pelvic floor after biofeedback therapy, when compared with those received Standard Therapy. Methods- Twenty-two Patients, with chronic constipation who fulfilled Rome diagnostic criteria for functional constipation for at least 12 weeks, participated in this study, they had a dyssynergic pattern of defecation i.e., paradoxical contraction or failure to relax the pelvic floor and anal muscles during defecation. The subjects are randomly assigned to receive either standard only (11 subjects) or biofeedback and standard (11 subjects) treatment for three months. Dynamic changes of pelvic floor(anorectal angle and perineal descent) at rest during squeezing and straining, are measured by MR defecography. Two MR defecography dynamic indices, including paradox index (abnormal anorectal angle change), and perineal descent index during simulated defecation, are measured before and after treatment. In order to assess the effects of biofeedback therapy in comparison with standard therapy on symptomatic changes, the quality of life and severity of depression ,a constipation scoring system according to Agachan Scoring System, the culturally adapted version of Short Form-36 and Beck Depression Inventory questionnaires are used respectively .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011020011N1**

Registration date: **2015-01-10, 1393/10/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-10, 1393/10/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-01-10, 1393/10/20

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of pelvic motion in patients with chronic constipation due to dyssynergic defecation after biofeedback therapy by MR defecography

Public title

Evaluation of patients with dyssynergic defecation after biofeedback therapy by MR defecography

Purpose

Treatment

Inclusion/Exclusion criteria

The Patients participate in this study, with chronic constipation who fulfill " Rome diagnostic criteria" for functional constipation for at least 12 weeks: they need to strain in defecation, have lumpy or hard stools, sensation of incomplete evacuation, and need manual maneuvers to facilitate defecation in more than 1/4 of bowel movements. They have a dyssynergic pattern of defecation. The patients also have diagnostic testing evidence (anorectal manometry or defecography or balloon expulsion test) of dyssynergic defecation. The diagnosis of paradoxical contraction of puborectalis muscle during straining is established by digital rectal examination. Patients were excluded from the study if they had previous anorectal surgery, anorectal tumors, or structural anorectal disorders, which needed operation intervention. Other exclusion criteria were significant cardiovascular, respiratory, neurologic, psychiatric illnesses, sever psychological problems, or endocrine and metabolic diseases that could cause constipation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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

Keshavarz Blvd.; Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2013-05-16, 1392/02/26

Ethics committee reference number

130/284/92/3

Health conditions studied**1****Description of health condition studied**

Chronic costipation and dyssynergic defecation

ICD-10 code

M62.9

ICD-10 code description

Disorder of muscle, unspecified

Primary outcomes**1****Description**

muscle function((Paradox index & perinal descend index)

Timepoint

before treatment and after its completion (3 months)

Method of measurement

MR defecography

Secondary outcomes**1****Description**

symptomatic changes

Timepoint

before tretment and after its completion

Method of measurement

costipation scoring questionnaire

2**Description**

The quality of life

Timepoint

before tretment and after its completion

Method of measurement

the culturally adapted version of Short Form-36

3**Description**

severity of depression

Timepoint

before tretment and after its completion

Method of measurement

, the culturally adapted version of Beck Depression Inventory questionnaires

Intervention groups

1

Description

For control group; standard therapy [The instructions regarding bowel habit, daily exercise (walking for 20 minutes), diaphragmatic breathing exercises (daily for 15 minutes, three times a day), dietary fiber and fluid intake, toilet timing (the patient was taught to attempt having a bowel movement at least twice a day, 30 minutes after meals or walking and consulted to avoid straining more than 5 minutes during defecation). If patients had no bowel movement for more than 48 hours, they were guided to use laxatives, such as polyethylene glycol. The patients were trained about the correct position of defecation. The duration is 3 months and the patients were supervised at least once a week over phone], cognitive-behavioral therapy (once a week).

Category

Rehabilitation

2

Description

For experimental group; biofeedback therapy(to correct the dyssynergic pattern of defecation, the patients should learn how to appropriately contract or relax anal and pelvic floor muscles, by visual and verbal feedback. A surface electrode on abdominal muscles and an interarectal pressure probe are used to monitor the activity of the muscles. Each biofeedback therapy session is performed 60 minutes twice a week for 12 sessions, then, once a week for 6 sessions, as a whole 18 sessions over 3 months.), exercise therapy (three times a day for ten minute), cognitive-behavioral therapy (once a week) and standard therapy .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Coloectal Clinic, Rasoul Akram Hospital, Iran University of Medical Sciences, Tehran, Iran.

Full name of responsible person

MrS Azeizkhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr.Sayed Ali Javad Moosavi

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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

Iran 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

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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