Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Name

Afsaneh Nikjooy

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

maroufi.n@iums.ac.ir

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/د

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

Street address

Satarkhan St.;Niyayesh St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Sayed Ali Javad Moosavi

Street address

Hemat ;Pardis:Iran University of Medical Sciences

City

Tehran

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

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Afsaneh Nikjooy

Position

Physiotherapy Clinical Instructor;Ph.D. Candidate

Other areas of specialty/work

Street address

Madadkaran; Shahnazari Av.; Madar Sq.; Tehran

City

Tehran

Postal code

Phone

+98 21 2222 7124

Fax

+98 21 2222 0946

Email

afsanehnikjooy@yahoo.com; maroufi.n@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Afsaneh Nikjooy

Position

Physiotherapy Clinical Instructor;Ph.D. Candidate

Other areas of specialty/work

Street address

Madadkaran St.; Shahnazari Av.; Madar Sq.;Tehran

City

Tehran

Postal code

Phone

+98 21 2222 7124

Fax

+98 21 2222 0946

Email

afsanehnikjooy@yahoo.com; maroufi.n@ums.ac.ir;

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Afsaneh nikjooy

Position

Physiotherapist; Clinical Instructor; Ph.D. Candidate

Other areas of specialty/work

Street address

Shahnazari St.;Madar Sq.;Mirdamad Blvd.;Tehran

City

Tehran

Postal code

Phone

+98 21 2222 7124

Fax

+98 21 2222 0946

Email

afsanehnikjooy@yahoo.com; maroufi.n@ums.ac.ir

Web page address

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