

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of exercise Therapy with Biofeedback & exercise Therapy with placebo feedback on signs & symptoms of patients with dyssynergic defecation

Protocol summary

Summary

Background: Biofeedback therapy is a selective treatment for anorectal dyssynergia. However, may be this kind of treatment such as others, has placebo effect. The aim of this study is a comparison between biofeedback therapy and placebo feedback dyssynergic defecation. Method: 30 patients were selected on the basis of ROMEIII inclusion criteria and were randomly placed in two groups to receive biofeedback & placebo feedback therapies. Then, comparing the ability to defecate the balloon (volume & time) before and after the treatment. Also, chief complain evaluated before and after both treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503016083N5**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name

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Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of exercise Therapy with Biofeedback & exercise Therapy with placebo feedback on signs & symptoms of patients with dyssynergic defecation

Public title

Efficacy biofeedback therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: all patients with anorectal dyssynergia. Exclusion criteria: mega colon; irritable colon syndrome; slow transit colon.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

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 Isfahan University of Medical Sciences

Street address

Department of Vice chancellor for research Isfahan University, Hazar garib Ave, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

392531 /16/5/1392

Health conditions studied

1

Description of health condition studied

Anorectal dyssynergia

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

ROMEIII

Timepoint

before & after treatment

Method of measurement

Questionnaire

2

Description

Ballon Volume (water)

Timepoint

before & after

Method of measurement

mililiter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Biofeedback therapy

Category

Rehabilitation

2

Description

Intervention group 2: placebo biofeedback

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar Hospital

Full name of responsible person

Ali Reza Pakghlab

Street address

Department physiotherapy, Ferozgar Hospital, Feroz Ave.

City

Teharn

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Payman Adibi

Street address

ISfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Isfahan 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 physical therapy, School of Rehabilitation Sciences, Isfahan University of Medical Sci

Full name of responsible person

Abbas Ali Pourmomeny

Position

PhD

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Postal code**Phone****Fax****Email****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