

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Effect of Biofeedback Therapy in Operated Patients with Laparoscopic Ventral Rectopexy Technique, due to Obstructive Defecation Syndrome

Protocol summary

Summary

The aim of this study is to search about the effect of biofeedback therapy in operated patients with laparoscopic ventral rectopexy technique, due to obstructive defecation syndrome. Some posters posted in surgery unit to announce these patients for attending in this study, in physiatry ward. People eligible for the study will be randomized into two groups. The total number of patients are 30, with 15 in each group. In the first group, exercises of pelvic floor muscles will be trained for 6 weeks with recommendations to improve the lifestyle, and in the second group all of these instructions will be concomitant with biofeedback therapy. 6 weeks after the end of biofeedback and exercise therapy, patients will be re- evaluated. The final results of the evaluation, is assessment of Wexner scoring system and parameters of pelvic floor contraction. Comparison of the patients who have participated in biofeedback therapy, with those in exercise therapy group, makes it possible to evaluate the efficacy of biofeedback therapy in reducing the recurrence of the disease and increasing the quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102024621N1**
Registration date: **2015-11-22, 1394/09/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-22, 1394/09/01

Registrant information

Name

Tannaz Ahadi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 8871 8207

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-11-02, 1394/08/11

Expected recruitment end date

2016-11-01, 1395/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Biofeedback Therapy in Operated Patients with Laparoscopic Ventral Rectopexy Technique, due to Obstructive Defecation Syndrome

Public title

The Effect of Biofeedback Therapy in Operated Patients, due to Obstructive Defecation Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: females older than 18 years old

;patients with ODS history who had operation with laparoscopic ventral rectopexy technique. Exclusion criteria: clinical evidence of external sphincter injury; fecal Incontinence; dyssynergic constipation.

Age

From **18 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Science

Street address

Medical faculty, Iran University of Medical Science,
Hemmat Hlgh way

City

Tehran

Postal code

Approval date

2015-10-20, 1394/07/28

Ethics committee reference number

IR.IUMS.REC.1394 .26352

Health conditions studied

1

Description of health condition studied

Chronic constipation

ICD-10 code

K59.0

ICD-10 code description

constipation

Primary outcomes

1

Description

Pelvic floor muscle contraction

Timepoint

After surgery, 1.5 month later, 3 month later

Method of measurement

Pelvic floor muscle contraction(hpa)

Secondary outcomes

1

Description

Score obtaining from Wexner scoring system

Timepoint

After surgery, 1.5 month later. 3 month later

Method of measurement

Wexner scoring system

Intervention groups

1

Description

In the first group exercises are training in pelvic floor muscles for 6 weeks with recommendations to improve the lifestyle. patients will be re- evaluated 6 and 12 weeks later.

Category

Treatment - Other

2

Description

In the second group biofeedback therapy will be done during 6 weeks. 6 weeks after the end of biofeedback therapy and exercise performances, patients will be re-evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Banafsheh Shahrami

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Pejman Madani

Street address

Hemmat high way, 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Tannaz Ahadi

Position

Physiatrist

Other areas of specialty/work

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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