

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of biofeedback in fecal incontinency treatment for patients with rectal cancer after inter-sphincteric resection

Protocol summary

Summary

The aim of this study is to search for the effect of biofeedback therapy in operated patients with rectal cancer due to fecal incontinency. 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 SF36 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: **IRCT2017053024621N7**

Registration date: **2017-07-26, 1396/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name

Tannaz Ahadi

Name of organization / entity

Iran University of Medical Science

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-11-25, 1395/09/05

Expected recruitment end date

2017-07-25, 1396/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of biofeedback in fecal incontinency treatment for patients with rectal cancer after inter-sphincteric resection

Public title

The effect of biofeedback in fecal incontinency treatment for patients with rectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: females older than 18 years old; patients with rectal cancer that had been under the inter-sphincteric resection operation; at least 4 weeks after surgery.

Age

From **18 years** old

Gender

Female

Phase

N/A

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 Sciences

Street address

Iran University of Medical Sciences, Hemmat High way

City

Tehran

Postal code**Approval date**

2017-02-14, 1395/11/26

Ethics committee reference number

IR.IUMS.REC.1395.9411524005

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

Faecal incontinence

ICD-10 code

R15

ICD-10 code description

Faecal incontinence

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 and SF36

Timepoint

After surgery, 1.5 month later, 3 month later

Method of measurement

Wexner scoring system and SF36

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 - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

Golnaz Raeisi

Street address

Froozgar Hospital, Behafarin St., Hafez Ave.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Pejman Madani

Street address

Hemmat high way

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
Iran University of Medical Sciences

Full name of responsible person
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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