

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluating the effect of biofeedback combined with diet in treatment of patients with constipation due to paradoxical contraction of the pelvic floor muscles

Protocol summary

Summary

Objectives: The purpose of the study is to assess the efficacy of biofeedback and regimen in the treatment of patients with constipation due to paradoxical pelvic floor movement. **Design:** This is an interventional study. **Setting and conduct:** Data include physical examinations, the results of manometry as well as tracking the status of clinical symptoms before and after treatment by CCF questionnaire. **Inclusion criteria:** Include diagnosis of constipation due to pelvic floor muscle disorders and digital rectal examination. **Exclusion criteria:** Inflammatory bowel disease, HIV infection, neurological disorders, urinary-stress incontinence, Urgency incontinence, Fecal incontinence. **Interventions:** group 1: Biofeedback + diet includes vegetables, drinking 6 to 8 glasses of water per day, psyllium powder 1 to 2 sachet per day, and walking three days a week, for half an hour every day group 2: Diet includes vegetables, drinking 6 to 8 glasses of water per day, psyllium powder 1 to 2 sachet per day, and walking three days a week, for half an hour every day. **Main outcome measures:** Constipation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102930545N1**
Registration date: **2017-04-29, 1396/02/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-29, 1396/02/09

Registrant information

Name

Tahereh Forooghifar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2365

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of biofeedback combined with diet in treatment of patients with constipation due to paradoxical contraction of the pelvic floor muscles

Public title

The effect of biofeedback combined with diet in treatment of patients with constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Terms of Inclusion: diagnosis of constipation due to pelvic floor muscle disorders, digital rectal examination.

Exclusion conditions: inflammatory bowel disease; HIV infection; neurological disorders, stress urinary incontinence, Urge Incontinence, fecal incontinence.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not 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

Imam Khomeini Hospital Complex, Keashavrz Blvd, Tehran

City

Tehran

Postal code

Approval date

2016-10-15, 1395/07/24

Ethics committee reference number

IR.TUMS.VCR.REC.1395.778

Health conditions studied

1

Description of health condition studied

constipation due to paradoxical contraction of the pelvic floor muscles

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

constipation

Timepoint

before the intervention, 3 months after beginning of the intervention, 6 months after beginning of the intervention, 1 year after beginning of the intervention

Method of measurement

Physical examination, the results of manometry as well as track the status of clinical symptoms before and after treatment by CCF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Biofeedback + diet includes vegetables, drinking 6 to 8 glasses of water per day, psyllium powder 1 to 2 sachet per day , and walking three days a week, for half an hour every day

Category

Lifestyle

2

Description

diet includes vegetables, drinking 6 to 8 glasses of water per day, psyllium powder 1 to 2 sachet per day , and walking three days a week, for half an hour every day

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Tahereh Forooghifar

Street address

Ayatollah Taleghani Hospital, Yaman Street,A'raabi street,Chamran Highway, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Tahereh Forooghifar

Street address

Valiasr Hospital, Imam Khomeini Hospital Complex,
Keshavarz Blvd., Tehran

City

Tehran

forooghifar.f@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Valiasr Hospital

Full name of responsible person

Dr Tahereh Forooghifar

Position

Gynecologist

Other areas of specialty/work**Street address**

Valiasr Hospital, Imam Khomeini Hospital Complex,
Keshavarz Blvd., Tehran

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Tehran

Postal code**Phone**

+98 21 6119 2365

Fax**Email**

forooghifar.f@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of
Medical Science

Full name of responsible person

Dr. Masoud Yoonesian

Street address

Central department of Tehran University of Medical
Sciences, Intersection of Keshavarz Blvd. and Qods
St.

City

Tehran

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, Tehran University of Medical
Science

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**

Valiasr Hospital

Full name of responsible person

Dr Tahereh Forooghifar

Position

Gynecologist

Other areas of specialty/work**Street address**

Valiasr Hospital, Imam Khomeini Hospital Complex,
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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