

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A randomized controlled trial of biofeedback for quality of life in women with stages I and II pelvic organ prolapse

Protocol summary

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Summary

women between ages 18-75 who have stage I and II pelvic organ prolapse, will be included. They will be randomized in two groups by simple randomization. One group will do pelvic floor exercises for 12 weeks while the other will do these exercises and biofeedback coincidentally. biofeedback will be done twice a week up to 8 sessions and so will last for 4 weeks. A questionnaire of quality of life will be filled in by the patients at the base time, 4 weeks and 12 weeks after randomization. Vaginal examination and measurement of pelvic muscles contraction pressure by the pressure biofeedback will be done at the same time. Finally the collected data will be analyzed.

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Of Iran University Of Medical Science, Dr Eftekhari Ardebili

Expected recruitment start date

2015-04-20, 1394/01/31

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020620980N1**

Registration date: **2015-04-17, 1394/01/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-17, 1394/01/28

Registrant information

Name

Neda Taghvadoost

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1612

Email address

Scientific title

A randomized controlled trial of biofeedback for quality of life in women with stages I and II pelvic organ prolapse

Public title

Effects of Biofeedback on pelvic organ prolapse

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: women with stages I and II pelvic organ prolapse; women between ages 18-75 Exclusion: a history of pelvic surgery or delivery during recent 6 months; pelvic cancer; inability to pelvic muscles contraction; a history of surgery for prolapse; any kind of low back pain which interfere the appropriate position for biofeedback; neurologic disorders; stages III and IV pelvic organ prolapse; a plan for pregnancy during next 2 months; any coincident therapies for prolapse; a plan of trip for more than 2 weeks during the intervention; Untreated UTI

Age

From **18 years** old to **75 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

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 Iran University Of Medical Science

Street address

Iran University Of Medical Science, Hemmat Freeway,
next to Milad Hospital

City

Tehran

Postal code

Approval date

2014-07-01, 1393/04/10

Ethics committee reference number

93/ D/105/1576

Health conditions studied

1

Description of health condition studied

peivic organ prolapse

ICD-10 code

XIV

ICD-10 code description

Diseases of the genitourinary system

Primary outcomes

1

Description

Quality of life

Timepoint

baseline, 4 weeks and 12 weeks after intervention
begins

Method of measurement

questionare

Secondary outcomes

1

Description

stage of prolapse

Timepoint

baseline, 4 weeks and 12 weeks after intervention
begins

Method of measurement

vaginal examination

2

Description

pelvic muscles contraction force

Timepoint

baseline, 4 weeks and 12 weeks after intervention
begins

Method of measurement

pressure biofeedback

Intervention groups

1

Description

Intervention: Biofeedback, Pelvic floor exercises, Life style
modification

Category

Rehabilitation

2

Description

Control: Pelvic floor exercises, Life style modification

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Neda.Taghvadoost

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University Of
Medical Science

Full name of responsible person

Dr Eftekhari Ardebili

Street address

Next to Milad hospital, Hemmat Autobahn

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 of Iran 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

Firoozgar Hospital

Full name of responsible person

Neda Taghvadoust

Position

physical medicine & Rehabilitation resident

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