

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of pelvic floor muscle training using biofeedback on the symptoms and quality of life of the women with pelvic organ prolapse

Protocol summary

2019-04-27, 1398/02/07

Study aim

Evaluation of the effect of pelvic floor muscle training using biofeedback on the symptoms of the women with pelvic organ prolapse

Design

The study only has an intervention group. sample size is 20.

Settings and conduct

Patients with pelvic organ prolapse will be referred by a gynecologist after an examination. Patients will be treated at the clinic of the Rehabilitation School of Isfahan University of Medical Sciences and by the responsible student. Treatment will be pelvic floor muscle training using biofeedback. The symptoms of prolapse and urinary incontinence will be measured before intervention and after 12 sessions of treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 20-70 years; Women with stage 2 or 3 prolapse Non-inclusion criteria: Women with neurological and psychological disorders

Intervention groups

This study has a group and its intervention, is pelvic floor muscle training using biofeedback.

Main outcome variables

Stage of prolapse; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180828040898N2**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **retrospective**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

Registrant information

Name

Zahra Gorji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5724 1347

Email address

zahra.gorji70@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2018-04-30, 1397/02/10

Actual recruitment end date

2018-09-21, 1397/06/30

Trial completion date

2018-10-23, 1397/08/01

Scientific title

Effect of pelvic floor muscle training using biofeedback on the symptoms and quality of life of the women with pelvic organ prolapse

Public title

The effect of biofeedback on the symptoms of the women with prolapse

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with pelvic organ prolapse Women aged 20 to 70 years

Exclusion criteria:

Breastfeeding previous prolapse surgery neurological and psychological disorders untreated urinary tract infection

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib street

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Isfahan

Province

Isfahan

Postal code

87713878710

Approval date

2017-01-14, 1395/10/25

Ethics committee reference number

IR.NUI.REC.1396.3.759

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

Pelvic Organ Prolapse

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Stage of pelvic organ prolapse

Timepoint

At the beginning of the study and 4 weeks later at the last treatment session

Method of measurement

Pelvic Organ Prolapse Quantification system

2**Description**

Quality of life

Timepoint

At the beginning of the study and 4 weeks later at the last treatment session

Method of measurement

Prolapse Quality of Life Questionnaire

Secondary outcomes**1****Description**

Symptoms of urinary incontinence

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms questionnaire

2**Description**

Pelvic floor muscle strength

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

Perineometer instrument

Intervention groups**1****Description**

Intervention group: In this group, patients will receive pelvic floor muscle training using biofeedback. Patients will be treated with Biofeedback for 4 weeks and 3 sessions each week. Each treatment session will be 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Zahra Gorji

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Soffe Ave., Azady Squar

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2

Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

Shahidbeheshty hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Abbas ali Pourmomeny

Street address

Hezar jarib Ave., Azady Squar., Kuye Emam
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Gorji

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Gorji

Position

Student