

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparative evaluation the effect of the pelvic floor muscle training and a novel approach of postural or positional inversion on the symptoms of the women with prolapse

Protocol summary

Study aim

Comparison of two methods of pelvic floor muscle training and a new postural method in the women with prolapse

Design

Two arm parallel group, randomized trial with blinded participant , responsible for collecting data and assessor. sample size is 40 people .

Settings and conduct

Women with prolapse regardless of symptoms will be enrolled by gynecologists. Patients will be treated at the clinic of the Rehabilitation School of Isfahan University of Medical Sciences and by the respective student. this study blinded with the participant, researcher, the person responsible for collecting.

Participants/Inclusion and exclusion criteria

People in study are the women with prolapse stage 2 or 3; and those with stages 1,0 and 4 are not included in this study.

Intervention groups

Control group intervention is pelvic floor muscle training with biofeedback. treatment of intervention group in addition to biofeedback is postural exercise .

Main outcome variables

Improvement the stage of prolapse in the Pelvic Organ Prolapse Quantification system

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180828040898N1**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

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

2018-01-25, 1396/11/05

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation the effect of the pelvic floor muscle training and a novel approach of postural or positional inversion on the symptoms of the women with prolapse

Public title

Evaluation the effect of exercise on prolapse

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with stage 2 or 3 prolapse Women aged 20 to 70 years old

Exclusion criteria:

Prolapse stage 0 ,1 ,4 Previous POP surgery Radiating back pain Pelvic cancer Psychiatric disorder Untreated urinary tract infection Planning to become pregnant during the next 6 months Inability to contract the pelvic floor muscle Breastfeeding

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study participant, responsible for data collection, Data Safety and Monitoring Committee are blind; Researcher and clinical care are not blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

Hezar jarib Ave., Azadi Squar., Kuye Emam Neighbourhood

City

Isfahan

Province

Isfahan

Postal code

87713-46173

Approval date

2018-01-20, 1396/10/30

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

N81.0

ICD-10 code description

Urethrocele

Primary outcomes

1

Description

Stage of pelvic organ prolapse in the Pelvic Organ Prolapse Quantification system

Timepoint

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

Method of measurement

Pelvic Organ Prolapse Quantification system

Secondary outcomes

1

Description

Urinary incontinence score based on ICIQ-FLUTS questionnaire

Timepoint

At the beginning of the intervention and 4 weeks later in the last treatment session .

Method of measurement

ICIQ-FLUTS questionnaire

Intervention groups

1

Description

Control group: Pelvic floor muscle training with biofeedback

Category

Rehabilitation

2

Description

Intervention group: Biofeedback plus postural exercise

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, Isfahan University of Medical Sciences

Full name of responsible person

Zahra Gorji

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Hezar jarib Ave., Azady Squar., Kuye Emam Neighbourhood

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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

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Hezar jarib Ave., Azady Squar., Kuye Emam Neighbourhood

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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

دانشجو

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available