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 Neibourhood

City

Isfahan

Province

Isfehan

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

Street address
Hezar jarib Ave., Azady Squar., Kuye Emam Neibourhood

City
Isfahan

Province
Isfehan

Postal code
87713-46173

Phone
+98 31 5724 1347

Email
Zahra.gorji70@ymail.com

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 Neibourhood

City
Isfahan

Province
Isfehan

Postal code
87713-46173

Phone
+98 31 5724 1347

Email
Zahra.gorji@ymail.com

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

Street address
Hezarjarib Ave., Azadi Squar., Kuye Emam Neighbourhood

City
Isfahan

Province
Isfehan

Postal code
87713-46173

Phone
+98 31 5724 1347

Email
zahra.gorji70@ymail.com

Person responsible for scientific 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

Street address
Hezar jarib Ave., Azady Squar., Kuye Emam Neibourhood

City
Isfahan

Province
Isfehan

Postal code
87713-46173

Phone
+98 31 5724 1347

Email
Zahra.gorji70@ymail.com

Person responsible for updating data

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
Street address
Hezarjarib Ave., AZadi Squar
City
Isfahan
Province
Isfehan
Postal code
87713-46173
Phone
+98 31 5724 1347
Fax
Email
Zahra.gorji70@ymail.com

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