Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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
2019-04-27, 1398/02/07

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 psychologichal 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

City
Isfahan

Province
Isfehan

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

2

Recruitment center
Name of recruitment center
Sedighe Tahere hospital
Full name of responsible person
Zahra Gorji
Street address
Khoram Ave., Jomhory Squar
City
Isfahan
Province
Isfehan
Postal code
87713-46173
Phone
+98 31 5724 1347
Email
Zahra.gorji70@ymail.com

3

Recruitment center
Name of recruitment center
Shahidbeheshty hospital
Full name of responsible person
Zahra Gorji
Street address
Motahhary Ave
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
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

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
Hezarjarib Ave., Azadi Squar
City
Isfahan
Province
Isfehan
Postal code
87713-46173
Phone
+98 31 5724 1347
Fax
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)
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