Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The Effect of Vaginal gel of Quercus (Oak Gal) on Pelvic Floor Muscle’s Strength and Sexual Function in Post- Menopausal Women

Protocol summary

Study aim
Determining the effect of oak Gall vaginal gel on pelvic floor muscle strength and sexual function in postmenopausal women

Design
Clinical trial with control group، parallel groups, Triple blind ، Randomized, Phase 3 on 100 patients. Random allocation is done using 4 blocks and a one-to-one allocation ratio, and individuals are divided into two groups of 50 people: intervention and control.

Settings and conduct
This study is performed on postmenopausal women referring to the menopausal clinic of Imam Khomeini Hospital in Ahvaz and is a triple blind study in which researchers, participants and statistical analysts are kept blind.

Participants/Inclusion and exclusion criteria
Menopausal women aged 45-65 years، Not menstruating for the past 12 months، Sexual Function score less than 26.5، Have literacy، Score 28 or less with the prinometer

Intervention groups
In this study, there are two groups of intervention and control. In the control group, postmenopausal women have the same conditions as the intervention group, but in the control group, placebo is used.

Main outcome variables
Increase pelvic floor muscle strength and improve postmenopausal women's sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200511047404N1**
Registration date: **2020-06-04, 1399/03/15**
Registration timing: **prospective**
Last update: **2020-06-04, 1399/03/15**
Update count: **0**

Registration date
2020-06-04, 1399/03/15

Registrant information

Name
Sahar Omidianpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3449 4135

Email address
omidianpour.s@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Vaginal gel of Quercus (Oak Gal) on Pelvic Floor Muscle’s Strength and Sexual Function in Post-Menopausal Women

Public title
The Effect of Quercus (Oak Gal) on Pelvic Floor Muscle and Sexual Function in Post- Menopausal Women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Not menstruating for the past 12 months Sexual Function score less than 26.5 Have literacy Score 28 or less with the prinometer
Exclusion criteria:
Chronic diseases Smoking and alcohol consumption Vaginal or cervical infection Getting uterine bleeding or spotting for an unknown reason Taking any type of vaginal medication Breast disease with a specific cause People with grade 3 and 4 pelvic floor muscle relaxation syndrome based on pop-Q Experiencing adverse or stressful events in a woman or her husband

Age
From **45 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Preparation of vaginal gel of oak Gall by pharmacist It will be built in the laboratory of Ahvaz School of Pharmacy. In order to reduce the likelihood of bias, allocation concealment selection is performed using unique codes in each of the treatments, so that the researcher and volunteers participating in the study and statistical analysis of the drug or the placebo of vaginal gels are completely unaware. Vaginal gel tubes are filled by the pharmacist.The vaginal gel of the oak Gall and the placebo are numbered and packaged in sequences in the similar envelopes, respectively. The drug envelopes are then given to control and intervention groups. Group allocation is random, and using locks of 4 and a one-to-one allocation ratio, individuals are divided into two groups of 50 intervention and control. To hide the allocation and prevent bias, the numbers of the intervention and control groups are placed in closed envelopes then are delivered to the eligible participants by the secretary of the menopausal clinic. Each person is given an envelope containing 1 60-gram tube of vaginal gel for 4 weeks to use, and the drug code is included. The person's checklist is recorded.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study is a triple-blind clinical trial study(researcher, participant, statistical analyst) and coding of vaginal gel tubes is done by a pharmacist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics in Biomedical Research

Street address
Golestan Blv, Nursing And Midwifery Department

City
Ahvaz

Province
Khouzestan

Postal code
6135539345

Approval date
2020-05-10, 1399/02/21

Ethics committee reference number
IR.AJUMS.REC.1399.128

Health conditions studied

1

Description of health condition studied
Loosening of the pelvic floor muscles

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Sexual Dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
pelvic floor muscle`s strength

Timepoint
Before the intervention, 4,8and 12 weeks after the start of use of the vaginal gel of the oak Gall

Method of measurement
prinometry

2

Description
Percentage of people with improved Sexual function

Timepoint
Before the intervention, 4,8and 12 weeks after the start of use of the vaginal gel of the oak Gall

Method of measurement
Sexual Function Index Questionnaire

3

Description
Sexual Function Score in the Sexual Function index Questionnaire
Timepoint
Before the intervention, 4,8and 12 weeks after the start of use of the vaginal gel of the oak Gall
Method of measurement
Questionnaire FSFI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vaginal gel with a concentration of 2.5% made in the laboratory of Ahvaz School of Pharmacy is given to postmenopausal women daily for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: The control group includes 50 samples that receive the placebo vaginal gel made in the laboratory of Ahwaz School of Pharmacy for 12 weeks and daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Menopause Clinic of the Imam Khomeini Hospital (Ahvaz Jundishapur University of Medical Sciences & H
Full name of responsible person
Sahar Omidianpour
Street address
Golestan Blv
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 2114
Email
omidianpour.2019@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Deputy Of Research And Technology
Street address
Golestan Blv
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3571 5794
Email
omidianpour.2019@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sahar Omidianpour
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Golestan Blv
City
Ahvaz
Province
Khouzestan
Postal code

6135715794

Phone
+98 61 3373 8333

Email
omidianpour.2019@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Parvaneh Mousavi

Position
Lecturer in Midwifery, Faculty member of Ahvaz Univercity of Medical Sience

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Golestan Blv

City
Ahvaz

Province
Khouzestan

Postal code
6135539345

Phone
+98 61 3373 8333

Email
mousavip2009@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Sahar Omidianpour

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Golestan Blv

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373833

Email
omidianpour.2019@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic information of individuals and data before and after the intervention is reported without mentioning the name.

When the data will become available and for how long
Access started in 1400.

To whom data/document is available
Only researcher in the filed of medical universities

Under which criteria data/document could be used
It can only be used in similar research

From where data/document is obtainable
Researcher's personal email

What processes are involved for a request to access data/document
According to the publication of the article and the registration of the information of the responsible author, the applicant will contact the responsible author to receive the data by academic email and the information will be sent after the approval of the academic email.

Comments