

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 pronometer

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

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Name of organization / entity

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy Of Research And Technology

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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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 field 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