

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of licorice vaginal cream and estrogen vaginal cream on the sexual function of postmenopausal women

Protocol summary

Study aim

Comparison of the effect of licorice vaginal cream and estrogen vaginal cream on the sexual function of postmenopausal women

Design

Clinical trial without control group, with two intervention groups, with parallel, randomized groups, phase 2 on 82 patients. Randomization was performed manually using the book Design and Analysis of a Clinical Trial by Joseph Philis, published in Willie Publications.

Settings and conduct

The study was conducted by referring to 7 health centers in Ilam and selecting postmenopausal women with sexual function problems. Visit to a gynecologist on days 1 (first day of referral and administration of the first dose of the drug), 14 (after the end of the first dose of the drug), 26 (ten days after the rest period, administration of the second dose of the drug), 40 (after re-use of the drug), 60 (2 months after the start of the first visit). The questionnaire will be completed on days 1 (first day of referral and before the intervention), 30 (one month after the start of the intervention), 60 (two months later).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- At least one year has passed since the onset of menopause and a maximum of 8 years since the onset of menopause, 2-Gynecologist confirms that menopause must have occurred, 3- Vaginal atrophy symptoms (dryness, paleness and Dyspareunia), 4- Married women, 5-Having sex at least twice a month during the study, 6- Reading and writing literacy, 7- Body mass index between 20 and 30, 8- Sexual dysfunction
Exclusion criteria: 1- Treatment with hormonal drugs, 2. Mental illness in the participant or his / her spouse, 3. Presence of underlying disease such as depression, cancers, pulmonary embolism, diabetes, 4. Taking anticholinergic drugs

Intervention groups

Study has two intervention groups, each with 41 members.

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047695N1**

Registration date: **2022-01-20, 1400/10/30**

Registration timing: **retrospective**

Last update: **2022-04-02, 1401/01/13**

Update count: **2**

Registration date

2022-01-20, 1400/10/30

Registrant information

Name

parisa ahmadizad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 84 3222 7567

Email address

p.ahmadizadd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2020-11-18, 1399/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of licorice vaginal cream and estrogen vaginal cream on the sexual function of postmenopausal women

Public title

Comparison of the effect of licorice vaginal cream and estrogen vaginal cream on the sexual function of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- At least one year has passed since the onset of menopause and a maximum of 8 years since the onset of menopause Gynecologist confirms that menopause must have occurred Vaginal atrophy symptoms (dryness, paleness and Dyspareunia) Married women Have sex at least 2 times a month during research Literacy for reading and writing Body mass index between 20 and 30 Sexual dysfunction

Exclusion criteria:

Treatment with hormonal drugs Mental illness in the participant or his / her spouse Underlying diseases such as depression, cancers, pulmonary embolism, diabetes Taking anticholinergic drugs

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked*No information***Sample size**

Target sample size: 82

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the finite randomization method because we want the study groups to have an equal sample size. One of the methods used for finite randomization is the block method. In this study, we use the quadratic block method. The four blocks will consist of two participants in the estrogen group and two participants in the licorice group. And the execution method will be that the possible modes for a block of 4 are 6 modes: a. aabb b. abab ج. abba د. bbaa ه. baba خ. baab and to generate random numbers, we use the online kitset software, by first registering the required values from 1 to 6 (number of numbers 6), and we repeat this 4 times, but in the fourth time the number We put the numbers instead of 6, 2, because in the first 3 times we have produced 18 numbers, and in the last step only 2 more numbers are needed, and thus 20 random numbers between 1 and 6 are produced, which indicate 4 blocks. According to each number, the treatment allocation list is determined. According to the number of samples, which is 82 people, we form 20

blocks of 4 and the last 2 people are randomly divided into two groups. (A = estrogen group, b = licorice group)

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ilam University of Medical Sciences

Street address

Tajarian6, Tajatian street, Chalimar

City

Ilam

Province

Ilam

Postal code

6931156381

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.MEDILAM.REC.1399.118

Health conditions studied**1****Description of health condition studied**

Sexual function of postmenopausal women

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes**1****Description**

Sexual function

Timepoint

During the study (first day of referral, 30 days after the start of the intervention, 60 days after the start of the intervention)

Method of measurement

Female Sexual function Index Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention Group: Receipt of vaginal licorice cream, prepared by the University Pharmacology Research Center, Approved dose of gynecologist, use at night with the applicator, The duration of use is 14 days, then 10 days of rest and 14 days of drug re-use.

Category

Treatment - Drugs

2

Description

Receiving 2% estrogen vaginal cream, Approved dose of gynecologist, use at night with the applicator, The duration of use is 14 days, then 10 days of rest and 14 days of drug re-use.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ilam Health Center

Full name of responsible person

Amin karimi

Street address

Khorramshahr Street, Ilam Health Center

City

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Province

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Postal code

6931853615

Phone

+98 84 3333 3127

Email

amin.karimy@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Kalvandi gholamreza

Street address

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ILAM

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6939177143

Phone

+98 84 3223 5724

Email

kalvandi-gh@medilam.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Parisa ahmadizad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoume shohani

Position

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Person responsible for updating data

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Parisa ahmadizad
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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

1-Study protocol 2- Study result

When the data will become available and for how long

After completing the study

To whom data/document is available

1- Faculty members 2- Clinical nurses 3- Medical and nursing students

Under which criteria data/document could be used

Access to data or documentation is possible for the following condition: 1- Use in future study resources 2- Future studies

From where data/document is obtainable

Please contact parisa ahmadizad Ahmadizad gmail:
P.ahmadizadd@gmail.com

What processes are involved for a request to access data/document

After sending the email to parisa ahmadizad, the email will be answered as soon as possible

Comments