Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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

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p.ahmadizaddd@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 womens 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 ز. 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
Ilam
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
Pajohesh blvd, Banganjab
City
ILAM
Province
Ilam
Postal code
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
Ilam University of Medical Sciences
Full name of responsible person
Masoume shohani
Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Tajarian6, chalimar

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Ilam

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Postal code

6931156381

Phone

+98 84 3222 7567

Email

p.ahmadizaddd@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

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.ahmadizaddd@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