

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of red clover vaginal cream on vaginal atrophy in postmenopausal women

Protocol summary

Study aim

Determine the effect of vaginal cream of red clover on vaginal atrophy in postmenopausal women

Design

In this study, 76 postmenopausal women attending the study who referred to Ahvaz Health Center No. 1 were selected and randomly assigned into two intervention and control groups, each assigned a code.

Settings and conduct

In this study, which has 3 sucrobers and in the field of healing in health center 1 of east of Ahwaz, researchers, pharmacists and participants are blind and coding of drugs will be done by the supervisor.

Participants/Inclusion and exclusion criteria

Participants of 76 randomly selected menopausal women and criteria for entering the study: 1. Age range 45 to 65 years 2. Breast-feeding men for at least one year or having a hormonal test with an FSH level higher than 40 international units and a spouse. 3. Having sexual activity 4. The presence of vaginal atrophy symptoms as well as exclusion criteria include: 1. Vaginal bleeding with unknown cause 2. Vaginal infection 3. Hormonal therapy or consumption of sex hormones 8 weeks before study 4. Use of isoflavones in the diet 5. No desire to continue the study company 6. A suspicious breast mass or breast cancer 7. Hospitalization during research

Intervention groups

Vaginal cream 2% red clover is a 8-week-old applicuer prepared from a dry extract of this plant and a placebo that is used in the same way as the intervention group and will be randomly distributed to the participants.

Main outcome variables

Vaginal atrophy, vaginal maturation, vaginal acidity, painful intercourse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038036N2**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **prospective**

Last update: **2018-01-11, 1396/10/21**

Update count: **1**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Jamileh Khayatan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3223 7134

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-08, 1396/11/19

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of red clover vaginal cream on vaginal atrophy in postmenopausal women

Public title

Phytoestrogenic treatment of vaginal atrophy in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range from 45 to 65 years Women with at least one year of menstruation or having a hormonal test with an FSH level higher than 40 international units with a spouse Having sexual activity The presence of vaginal atrophy

Exclusion criteria:

Vaginal bleeding with unknown cause Vaginal infection Hormone therapy or use of sex hormones 8 weeks before study Taking isoflavones in the diet History of suspected breast mass or breast cancer Hospital admission during research Unwillingness to continue the study company

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the clinical trial is 3 blind and the total number of samples is 76, randomization is performed using computer software of random numbers. The subjects are divided into two groups of intervention and control, 38 of which were first to the intervention group and 38 The second number belongs to the control group

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the drugs are made by the pharmacist and coded and packaged by the supervisor, the researchers, the pharmacist and the participants are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz, University of Medical Sciences, Assistant Professor of Research and Information Technology, Jundishapur University of Medical Sciences, Ahvaz, Ground floor

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Province

Khuzestan

Postal code

613515794

Approval date

2017-12-17, 1396/09/26

Ethics committee reference number

IR.AJUMS.REC.1396.728

Health conditions studied

1

Description of health condition studied

Vaginal Atrophy

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

Vaginal atrophy

Timepoint

Before intervention, after intervention

Method of measurement

Vaginal smear

Secondary outcomes

1

Description

Dyspareunia

Timepoint

Before the intervention, two weeks after the intervention, four weeks after the intervention, eight weeks after the intervention

Method of measurement

4 degree self-rating scale

2

Description

Sexual performance

Timepoint

Before and after intervention

Method of measurement

Female Sexual Function Index (FSFI)

3

Description

Sexual satisfaction

Timepoint

Before and after the intervention

Method of measurement

Larsson Sexual Satisfaction Questionnaire

4

Description

Severity of menopause symptoms

Timepoint

Before the intervention, two, four, and eight weeks after the intervention

Method of measurement

Menopause Rating Scale Questionnaire

Intervention groups

1

Description

Intervention group: Red clover vaginal cream 2% One application once a day for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo, vaginal cream, once a day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Health Center No. 1 in Ahvaz

Full name of responsible person

Jamileh Khayatan

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Ayatollah Behbahani Expressway, opposite the Haft-e Tir Park

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2

Recruitment center**Name of recruitment center**

Women's Clinic of Ahvaz Imam Khomeini Hospital

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

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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

Jamileh khayatan

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Undecided - It is not yet known if there will be a plan to make this available