

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison the effect of Glycyrrhiza glabra and placebo vaginal creams on treatment of vaginal atrophy in postmenopausal women

Protocol summary

Summary

Objective: comparison the effect of Glycyrrhiza glabra and placebo vaginal creams on treatment of vaginal atrophy in postmenopausal women Design: double blind randomized clinical trial Randomization: Subjects will allocate to two equal groups of inhalation and intravenous fentanyl according to table of random numbers. Participants including major eligibility criteria: this study will conduct on 70 postmenopausal women refer to Izeh Health Centers. Main inclusion criteria include having sexual activity and single partner; passing at least 12 months of amenorrhea; presence of vaginal atrophy symptoms; normal blood pressure and main exclusion criteria include genital abnormalities; breast diseases with unknown reason; vaginal infection needing treatment; genital bleeding or spotting with unknown reason; hormone therapy or using sex hormones within the 2 months before the study and using of phytoestrogens such as soy, red clover, fenugreek, and vitex within the last one month. Main outcome: vaginal atrophy Intervention: Subjects in intervention group will receive one time in each night Glycyrrhiza glabra vaginal cream 2% using an applicator for 8 weeks. Subjects in control group will receive one time in each night placebo vaginal cream using an applicator for 8 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010331739N1**

Registration date: **2017-01-27, 1395/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-27, 1395/11/08

Registrant information

Name

Mastaneh Sadeghi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8331

Email address

sadeghi.ma@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-01-09, 1395/10/20

Expected recruitment end date

2017-04-09, 1396/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Glycyrrhiza glabra and placebo vaginal creams on treatment of vaginal atrophy in postmenopausal women

Public title

The effect of Glycyrrhiza glabra vaginal cream on treatment of vaginal atrophy of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women with sexual activity and single partner; passing at least 12 months of amenorrhea;

presence of vaginal atrophy symptoms; normal blood pressure. Exclusion criteria: Genital abnormalities; breast diseases with unknown reason; liver cholestatic disorders; renal failure; vaginal infection needing treatment; genital bleeding or spotting with unknown reason; hormone therapy or using sex hormones within the 2 months before the study; using of phytoestrogens such as soy, red clover, fenugreek, and vitex within the last one month; body mass index more than 30 kilogram per cubic meter. .

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

City

Ahvaz

Postal code

6135715749

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

555IR.AJUMS.REC.1395

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 acidity

Timepoint

Before and after intervention

Method of measurement

By PH strip

2

Description

subjectiv symptoms of vaginal atrophy

Timepoint

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

Method of measurement

Kupperman index questionnaire

3

Description

Dyspareunia

Timepoint

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

Method of measurement

Dyspareunia self-administered scale

4

Description

Vaginal dryness

Timepoint

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

Method of measurement

Vaginal dryness self-administer scale

5

Description

Percent of vaginal cells maturation

Timepoint

Before and after intervention

Method of measurement

Vaginal smear

Secondary outcomes

1

Description

Sexual function

Timepoint

Before and after intervention

Method of measurement

Female sexual function index questionnaire

2**Description**

Sexual satisfaction

Timepoint

Before and after intervention

Method of measurement

Larson's sexual satisfaction questionnaire

Intervention groups**1****Description**

Subjects in intervention group will receive one time in each night Glycyrrhiza glabra vaginal cream 2% using an applicator for 8 weeks.

Category

Treatment - Drugs

2**Description**

Subjects in control group will receive one time in each night placebo vaginal cream using an applicator for 8 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Izeh Health Center number 1

Full name of responsible person

Mastaneh Sadeghi

Street address

Next to Baharan park, Izeh, Khuzestan

City

Izeh

2**Recruitment center****Name of recruitment center**

Izeh Health Center number 2

Full name of responsible person

Mastaneh Sadeghi

Street address

Emam Khomeini square, Izeh, Khuzestan

City

Izeh

3**Recruitment center****Name of recruitment center**

Izeh Health Center number 3

Full name of responsible person

Mastaneh Sadeghi

Street address

Next to Behvarzi academy, Behvarzi street, Izeh, Khuzestan

City

Izeh

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences

Full name of responsible person

Behzad Sharif Makhmal Zadeh

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Ahwaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

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Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

ahra Abbaspoor

Position

Ph.D in Reproductive Health

Other areas of specialty/work**Street address**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty