

# 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

**Street address**

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

**City**

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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## Person responsible for scientific inquiries

**Contact**

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**Position**

Ph.D in Reproductive Health

**Other areas of specialty/work**

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## Person responsible for updating data

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Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Mastaneh Sadeghi

**Position**

MSc of midwifery

**Other areas of specialty/work**

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**Email**

sadeghi.ma@ajums.ac.ir; sadeghi33708@yahoo.com

**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*