

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison the effect of Chamomile vaginal gel with Conjugated Estrogen in the treatment of vaginal atrophy in postmenopausal women

#### Protocol summary

##### Study aim

The aim of this study is to compare the effect of chamomile vaginal gel with Conjugated Estrogen on the treatment of vaginal atrophy in postmenopausal women.

##### Design

In this study 96 postmenopausal women with vaginal atrophy and have include criteria into the study, are randomly divided into two intervention groups and one control group.

##### Settings and conduct

Samples include postmenopausal women aged 45 to 65 with vaginal atrophy. The sample size is 96 and the duration of the intervention is 12 weeks. Researcher and volunteer Participation in this study is completely unaware from vaginal medications and placebo, and medications tubes fill with pharmacist. Vaginal medications are all in the same package and are coded by the pharmacist. Initially, patients are examined from the symptoms of vaginal atrophy and the questionnaire of mental symptoms of vaginal atrophy is completed by patients. then The vaginal discharge samples are taken for examination of the Vaginal mucosal cell maturation index. The pH of the vagina is also measured by a pH meter. Individuals are randomly assigned to one of three groups. One group (Vaginal Cream, Conjugate estrogen) another group (chamomile vaginal gel) and the control group (placebo vaginal gel) received at a dose of 1 mg for 12 weeks ( First two weeks every night and the next 10 weeks twice a week). End of weeks 2, 6, and 12 are evaluated for signs of vaginal atrophy. at the end of the study, the vaginal pH and vaginal discharge samples are examined.

##### Participants/Inclusion and exclusion criteria

include criteria: People who have had at least one year of their last menstruation or have a hormonal test with an average fsh > 40 international units There are symptoms of vaginal atrophy The age range is 45-65 years Have sex and monogamy exclude criteria: Vaginal infection needs treatment Genital abnormalities Hormone therapy

or use sexual hormones during the 8 weeks prior to the study Using vaginal medicines or any lubricant at least 15 days before the study Tobacco use (alcohol, cigarette and hookah) Breast diseases with unknown cause Uterine bleeding or spotting with unspecified cause Excessive consumption of phytoestrogens such as soy, red clover, fenugreek over the past month BMI more than 30 Cholestatic Diseases of the Liver Severe kidney failure Acute Thrombophlebitis High blood pressure

##### Intervention groups

One group (vaginal cream conjugate estrogen); another group( chamomile vaginal gel) and the control group (placebo vaginal gel)

##### Main outcome variables

Treatment of vaginal atrophy; Reducing the complications of vaginal atrophy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171218037943N1**

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

Registration timing: **registered\_while\_recruiting**

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

Update count: **0**

##### Registration date

2018-01-21, 1396/11/01

##### Registrant information

##### Name

Zahra Bosak

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3636 3453

##### Email address

zahrabosak@gmail.com

**Recruitment status**

Recruitment complete

**Funding source**

**Expected recruitment start date**

2018-01-21, 1396/11/01

**Expected recruitment end date**

2018-06-20, 1397/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of Chamomile vaginal gel with Conjugated Estrogen in the treatment of vaginal atrophy in postmenopausal women

**Public title**

Vaginal gel Chamomile and Conjugated Estrogen in the treatment of vaginal atrophy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

People who have had at least one year of their last menstruation or have a hormonal test with an average fsh> 40 international units There are symptoms of vaginal atrophy The age range is 45-65 years Have sex and monogamy

**Exclusion criteria:**

Vaginal infection needs treatment Genital abnormalities Hormone therapy or use of sexual hormones during the 8 weeks prior to the study Using vaginal medicines or any lubricant at least 15 days before the study Tobacco use (alcohol, cigarette and hookah) Breast diseases with unknown cause Uterine bleeding or spotting with unspecified cause Excessive consumption of phytoestrogens such as soy, red clover, fenugreek over the past month BMI more than 30 Cholestatic Diseases of the Liver Severe kidney failure Acute Thrombophlebitis High blood pressure

**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: 96

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomized numerical tables using computers. individually

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Researcher and volunteer in this study completely unaware of the placebo or medications and medication tubes filled by the pharmacist. Vaginal medications are in the same package and are coded by the pharmacist.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Associate Professor of Research and Information Technology, Ahvaz Jundishapur University of Medical Sciences, Academic town, Ahvaz

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Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Approval date**

2017-11-11, 1396/08/20

**Ethics committee reference number**

IR.AJUMS.REC.1396.729

**Health conditions studied**

**1**

**Description of health condition studied**

Vaginal Atrophy in Postmenopausal Women

**ICD-10 code**

N95.2

**ICD-10 code description**

Postmenopausal atrophic vaginitis

**Primary outcomes**

**1**

**Description**

vaginal atrophy

**Timepoint**

At the beginning of the study, 14, 42 and 84 days after

Intervention

**Method of measurement**

Cooperman Index Questionnaire

**2**

**Description**

Percentage of vaginal cell maturation

**Timepoint**

Before intervention, after intervention

**Method of measurement**

Vaginal smear

**3**

**Description**

Vaginal acidity

**Timepoint**

Before intervention, after intervention

**Method of measurement**

PH gauge

**Secondary outcomes**

**1**

**Description**

Painful intercourse

**Timepoint**

At the beginning of the study, 14, 42 and 84 days after Intervention

**Method of measurement**

Self-assessment scale is 4 degrees

**2**

**Description**

Menopause symptoms

**Timepoint**

At the beginning of the study, 14, 42 and 84 days after Intervention

**Method of measurement**

Cooperman Index Questionnaire

**3**

**Description**

Severity of menopause symptoms

**Timepoint**

At the beginning of the study, 14, 42 and 84 days after Intervention

**Method of measurement**

Menopause Rating Scale

**4**

**Description**

Sexual performance

**Timepoint**

Before and after the intervention

**Method of measurement**

Female Sexual Function Index (FSFI)

**5**

**Description**

Sexual satisfaction

**Timepoint**

Before and after the intervention

**Method of measurement**

Larson Sexual Satisfaction Questionnaire

**Intervention groups**

**1**

**Description**

First intervention group: Vaginal Cream, Conjugated Estrogen .625 Mg, one mg for 12 weeks (the first two weeks, each night and the next 10 weeks, two nights a week), Aburaihan Pharmacy Company

**Category**

Treatment - Drugs

**2**

**Description**

Two intervention group: chamomile vaginal gel 5%, one mg for 12 weeks (the first two weeks, each night and the next 10 weeks, two nights a week)

**Category**

Treatment - Drugs

**3**

**Description**

Control group: placebo vaginal gel, one mg for 12 weeks (the first two weeks, each night and the next 10 weeks, two nights a week)

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health Center Number One

**Full name of responsible person**

Zahra Bosak

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Imam street, Gotvand County

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Badvi

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**Email**

itc@ajums.ac.ir

**Web page address**

<http://behsan.ajums.ac.ir/>

**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

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Zahra Bosak

**Position**

Masters Student of Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

No - There is not 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