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)

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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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Khouzestan
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
Masters Student of 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
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