Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of Centella Asiatica and Conjugated estrogen vaginal cream for the treatment of vaginal atrophy in postmenopausal women

Protocol summary

Study aim

General purpose:Comparing the Effect of Centella Asiatica and Conjugated Estrogen Vaginal Cream for the Treatment of Vaginal Atrophy in Postmenopausal Women specific objecvtive: Comparison of vaginal atrophy Improvement before intervention as well as 4 and 8 weeks after intervention in Centella Asiatica group Comparison of vaginal atrophy Improvement before intervention as well as 4 and 8 weeks after intervention in Conjugated Estrogen group Comparison of vaginal atrophy Improvement before intervention as well as 4 and 8 weeks after intervention in two groups

Design

Single-blind randomized controlled Clinical trial

Settings and conduct

Selected health centers and gynecologic clinics of hospitals affiliated to Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria

Being Iranian and residence of Mashhad,Iran Married and Sexually active women, age range of 40–65 years, Having reading and writing skills, Having amenorrhea for at least 12 months , or 6 months amenorrhea with FSH>40 or an endometrial thickness of 5 mm or less as determined by trans vaginal ultrasonography, Getting a score of ≥ 65 on the visual analogue scale (VAS) , Having at least one symptom of physical examination scale ,having a vaginal pHvalue > 5 , Having vaginal maturation index more than 50 percent

Intervention groups

The intervention group will receive 1% Centella Asiatica Vaginal Cream daily for 8 weeks and the usual treatment group will receive 0.625 mg of conjugated estrogen cream daily for two weeks,and then twice a week.

Main outcome variables

Most bothersome symptom(MBS),Physical examination scale,Vaginal pH Vaginal maturation index(VMI),Vaginal maturation value(VMV)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180501039490N1**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-06, 1397/03/16**
Update count: **0**

Registration date

2018-06-06, 1397/03/16

Registrant information

Name

Mahnaz Rahmanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effect of Centella Asiatica and Conjugated estrogen vaginal cream for the treatment of vaginal atrophy in postmenopausal women

Public title
Comparing the effect of Centella Asiatica and Conjugated estrogen vaginal cream for the treatment of vaginal atrophy in postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being Iranian and residence of Mashhad,Iran Married and Sexually active women age range of 40–65 years Having reading and writing skills Having amenorrhea for at least 12 months , or 6 months amenorrhea with FSH>40 or an endometrial thickness of 5 mm or less as determined by transvaginal ultrasonography Getting a score of ≥ 65 on the visual analogue scale (VAS) and having at least one symptom of physical examination scale and a vaginal pH value > 5 and Vaginal maturation index(VMV) < 50

Exclusion criteria:
Current or suspected endometrial cancer Suspected genital cancer Reproductive system abnormalities Genital bleeding with unknown causes Use of anti hypertensive drugs Smoking or passing at least 3 months after smoking ceasation Vaginal infections Use of hormone replacement therapy 8 weeks before the study Use of foods containing 40 to 60 grams (about one tbsp) of phyto estrogen (such as red clover, flaxseeds and soy beans) in the past month Having conditions such as diabetes, chronic renal disease, arthritis, cardiovascular diseases, and active disease in the liver or gallbladder

Age
From **40 years** old to **65 years** old

Gender
Female

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation will be done by typing on the code assigned to the Centella Asiatica cream and the conjugated estrogen cream. These codes are wrriten on two peaces of papers which are place in one box. At the first day of sampling, the researcher takes one of the papers inside the box , which will be assigned to the first sample,and the other code will be allocated to the next sample(control). In this way, subjects will be assigned to intervention and control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Similarity of creams in terms of shape, color and size of cream-containing shells

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Research Ethics Committee of Mashhad University of Medical Sciences

Street address
Daneshgah Ave, Mashhad,Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2018-04-21, 1397/02/01

Ethics committee reference number
شماره IR.MUMS.REC.1397.019

Health conditions studied

1

Description of health condition studied
Vaginal Atrophy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
vaginal pH

Timepoint
Beforeas well as 4 and 8 weeks after starting the intervention

Method of measurement
Merk PH-indicator strips

2

Description
vaginal maturation value (VMV)

Timepoint
Beforeas well as 4 and 8 weeks after starting the intervention

Method of measurement
Pathological examination

3

Description
vaginal maturation index (VMI)
Timepoint
Beforeas well as 4 and 8 weeks after starting the intervention
Method of measurement
Pathological examination

Secondary outcomes

1

Description
most bothersome symptom(MBS)
Timepoint
Beforeas well as 4 and 8 weeks after starting the intervention
Method of measurement
Visual Analogue Scale

2

Description
Vaginal physical examination
Timepoint
Beforeas well as 4 and 8 weeks after starting the intervention
Method of measurement
physical examination scale

Intervention groups

1

Description
Intervention group: Centlla Asiatica Cream 1% , daily for 8 weeks as an applicator, produced in the laboratory of school of Pharmacy, Mashhad University of Medical Sciences, Mashhad,Iran
Category
Treatment - Drugs

2

Description
Control group: Conjucated estrogen cream
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Nafise Saghafi
Street address
Ahmad Abad Ave,Ghaem Hospital,Mashhad,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
prof.Mohsen Tafaghodi
Street address
school of Pharmacy,University campus(pardis),Vakil Abad Blvd,Mashhad,Iran
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17871 91886
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TafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahnaz Rahmanpour

Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"No more information"
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available