Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Ointment Containing Hops Nanoparticles for Relieving Early Menopausal Symptoms

Protocol summary

Summary

Objectives: To evaluate the effectiveness of an ointment containing hops nanoparticles in the alleviation of early menopause symptoms. Design: Double-blind randomized controlled clinical trial. Setting and Conduct: After preparation of an ointment containing hops nanoparticles, drug toxicity evaluation using cell cultures, and in vivo cytotoxicity assessments using an animal model, the third phase of the study will be initiated. During this phase, 60 women with menopause symptoms will be recruited in a double-blind randomized clinical trial study. The participants will be selected through purposive sampling and randomly allocated to intervention and control groups to receive the prepared ointment (containing hops nanoparticles) and placebo, respectively. The women will be asked to apply the ointments once daily for 12 weeks. Participants: This study will include 45-60-year-old women with early symptoms of menopause. The inclusion criteria will be 12-24 months since the onset of menopause, no hormone therapy during the six months before the study, no allergy to phytoestrogens, and no history of undiagnosed abnormal uterine bleeding, breast or uterine cancer, and thromboembolic, cerebrovascular, and coronary heart disorders. Interventions: The intervention group will apply the ointment containing hops nanoparticles on their arm once daily for 12 weeks. The control group will follow the same procedure using a placebo ointment. Main Outcome Measures: Early menopause symptoms will be assessed through the Menopause Rating Scale (MRS). Clinical and immunological parameters, along with serum estradiol levels, will also be measured. All measurements will be performed before and after the intervention and the obtained values will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062526405N1**
Registration date: **2016-07-09, 1395/04/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-09, 1395/04/19

Registrant information

Name
Fatemeh Abdi
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 2243 2500
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abdi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Source of funding is provided by Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Ointment Containing Hops Nanoparticles

for Relieving Early Menopausal Symptoms

Public title
Effectiveness of Ointment Containing Hops Nanoparticles for Relieving Early Menopausal Symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: • last menstrual period between 12 months and 2 years before the beginning of the study ; • age between 45 and 60 years; • not using of any hormone replacement therapies in the past 6 months; • Not having any allergic disorders to phytoestrogens; • not having abnormal uterine bleeding, breast cancer and uterine cancer; • not having a past history of breast cancer, endometrial cancer, thromboembolism disorders and coronary heart disease; • not having any chronic dermatologic disorders. Exclusion criteria: Patients presenting with systematic illness, allergic reactions ,and use of any interfering drugs were excluded.
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
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 Shahid Beheshti University of Medical Sciences
Street address
Chamran Highway, Yemen Street, Arabi Street
City
Tehran
Postal code
193954763
Approval date
2016-05-17, 1395/02/28
Ethics committee reference number
IR.SBMU.ENDOCRINE.REC.1395.163

Health conditions studied

1

Description of health condition studied
Menopause
ICD-10 code
N95.1 ,N95
ICD-10 code description
Menopausal and female climacteric states , Other specified menopausal and perimenopausal disorders

Primary outcomes

1

Description
Early Menopausal Symptoms
Timepoint
before-after
Method of measurement
Menopausal Rating Scale

Secondary outcomes

1

Description
stradiol level
Timepoint
before-after
Method of measurement
biochemical tests

2

Description
cytokine profile
Timepoint
before-after
Method of measurement
inflammatory index analysis

Intervention groups

1

Description
topical ointment containing Hops nanoparticles on skin of arm, per day, during 12 weeks
Category
Treatment - Drugs

2

Description
topical ointment containing placebo on skin of arm, per day, during 12 weeks

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Institute for Endocrine Sciences
Full name of responsible person
Fatemeh Abdi
Street address
No.24 Arabi Street- Yemen Street - Velenjak- Tehran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor in Research Affairs Research Institute for Endocrine Sciences, Shahid Beheshti Unive
Full name of responsible person
Dr.Zadeh Vakili
Street address
No.24 Arabi Street- Yemen Street - Velenjak- Tehran.
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor in Research Affairs Research Institute for Endocrine Sciences, Shahid Beheshti Unive
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
Shahid Beheshti University of Medical Sciences
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Fatemeh Abdi
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Reproductive Endocrinology Research Center
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Dr.Fahimeh Ramezani Tehrani
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Person responsible for updating data

Contact

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