Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Humulus Lupulus on early menopausal symptoms in menopausal and perimenopausal women: A Randomised Controlled Trial

Protocol summary

Summary

This study aims to determine the effect of Humulus Lupulus on early menopause symptoms in menopausal and perimenopausal women. Design: Two parallel arm Randomized Controlled Trial. Setting and conduct: This study will be conducted in health centers of Tabriz city-Iran. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Eligible women will be randomly assigned into two groups of 60 subjects with block sizes of 4 and 6, stratified by menopausal status. Participants: 120 menopausal or perimenopausal married women aged 40 to 60 years old suffering from early menopause symptoms. Interventions: The intervention group will receive Humulus Lupulus tablet daily for 90 days and the control group will receive placebo tablet daily for 90 days. To ensure of taking of drugs, the researcher will contact with participants during 2, 6 and 10 weeks by phone. Main outcome measures: Early menopause symptoms and hot flushes number will be assessed by the Greene Scale and checklist respectively at baseline, 4, 8 and 12 weeks after starting the intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010110324N7**
Registration date: **2013-04-10, 1392/01/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-04-10, 1392/01/21

Registrant information

Name
Mojgan Mirghafourvand
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Humulus Lupulus on early menopausal symptoms in menopausal and perimenopausal women: A Randomised Controlled Trial

Public title

Effect of Humulus Lupulus on early menopausal symptoms in menopausal and perimenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Married women aged 40 to 60 years; Willingness to participate in the study; Complaining of

hot flashes; having literacy and being able to answer questions; having a Phone; having a score greater than 15 and less than 42 based on Greene scale. Exclusion criteria: Taking drugs including sulfonamides, methotrexate, triamterene, sulfasalazine, estrogen, phenytoin, benzodiazepines, antidepressants, antithyroid, chemical drugs and multivitamin; hormone therapy and the use of OCP during the last 3 months, using vegetable alternative supplement for vasomotor symptoms during the past month; Contraindications of hormone therapy including suspected or known breast or endometrial cancer, undiagnosed abnormal vaginal bleeding, active thromboembolic disorders and active disease of liver or gallbladder; sensitive to lactose; use of medicines that cause hot flushes including breast cancer treatment drugs like letrozole, raloxifene, amlodipine, Bethanecol, hydrochloride, desmopressin and calcitonin.

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City
Tabriz

Postal code

Approval date
2013-02-18, 1391/11/30

Ethics committee reference number
91209

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
Total and subdomains scores of early menopause symptoms in perimenopausal women

Timepoint
Before intervention, 4, 8 and 12 weeks after intervention

Method of measurement
Greene scale

2

Description
Total and subdomains scores of early menopause symptoms in postmenopausal women

Timepoint
Before intervention, 4, 8 and 12 weeks after intervention

Method of measurement
Greene scale

3

Description
Frequency of hot flashes in perimenopausal women

Timepoint
Before interventions, 4, 8 and 12 weeks after intervention

Method of measurement
Checklist for daily counts

4

Description
Frequency of hot flashes in postmenopausal women

Timepoint
Before intervention, 4, 8 and 12 weeks after intervention

Method of measurement
Checklist for daily counts

Secondary outcomes

1

Description
Comparison of the effect of Humulus Lupulus on early menopause symptoms and frequency of hot flushes in postmenopausal and perimenopausal women
Timepoint
4, 8 and 12 weeks after intervention
Method of measurement
Greene scale and Checklist for daily counts

Intervention groups

1

Description
The intervention group will receive 500 mg Humulus Lupulus tablet daily for 90 days. Glandular powder separated from the strobiles of the Humulus lupulus (hops) plant will be used for making tablets
Category
Treatment - Drugs

2

Description
The control group will receive 500 mg placebo tablet daily for 90 days. Placebo tablets contain lactose
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz health centers
Full name of responsible person
Aghamiri Vida
Street address
Nursing & Midwifery Faculty, South Shariati Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Shakouri Seyyed Kazem
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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
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, Tabriz 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
Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences
Full name of responsible person
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Person responsible for scientific inquiries

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Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mozhgan Mirghafourvand
Position
PhD of reproductive health
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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