

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 envelopes 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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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

Street address

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

Aghamiri Vida

Position

MSc student in Midwifery

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mozghan Mirghafourvand

Position

PhD of reproductive health

Other areas of specialty/work

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Web page address<http://nursing.tbzmed.ac.ir>**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*