

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison of the impact of oral capsule hypericum perforatum and matricaria camomil on hot flashes and sleep disorder in perimenopausal women

Protocol summary

Summary

The aim of this study is to compare the effectiveness of oral capsules of Matricaria chamomile and Hypericum perforatum on hot flashes and women's sleep disorders in menopause. This study is a randomized clinical trial, double-blind, placebo-control. The samples are postmenopausal women aged 45 to 60. The inclusion criteria consist of: having menopausal symptoms for at least 3 months, not receiving hormone therapy in the last 3 months, not suffering from any systemic disease, not taking benzodiazepines, anticoagulants and hypnotic drugs, non-smoking. The exclusion criteria are: receiving Anxiolytic drugs, hypnotic, anticoagulants, phytoestrogens and hormone therapy, development of abnormal uterine bleeding and any systemic disease during the study. The sample size is 123 women and the intervention period is 8-weeks. The demographic and daily Hot Form questionnaires as well as, the Pittsburgh Sleep will be filled out by each sample a week before the intervention. The samples are randomly divided into three separate groups. Similarly, the medicaments, are accidentally distributed into three groups by the pharmacist as follows: One group will receive capsules of chamomile total daily dose of 500 mg twice a day, next group of Hypericum total daily dose of 900 mg twice a day and the control group capsules containing starch, twice a day for 8 weeks. After 4 and 8 weeks participants will complete the questionnaires again. The outcome of the study reveals an improvement and better adaptability menopausal symptoms through use of herbal remedies and dietary supplements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307302751N9**

Registration date: **2014-01-20, 1392/10/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-20, 1392/10/30

Registrant information

Name

Masoomeh Kheirkhah

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

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+98 21 8247 1000

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the impact of oral capsule hypericum perforatum and matricaria camomil on hot flashes and

sleep disorder in perimenopausal women

Public title
A comparison of the impact of oral capsule hypericum perforatum and matricaria camomil on hot flashes and sleep disorder in perimenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age 45 to 60 years; Having menopausal symptoms for at least 3 months ;Complaining of hot flashes, at least 3 times a day ;Complaining of sleep disturbance for at least 3 months; Total sleep time less than 6 hours ;Not receiving hormone therapy within the last 3 months ;Not receiving treatment for menopause symptoms; Not receiving phytoestrogens such as Soya ;No Heart disease, hypertension, diabetes, epilepsy, any mental illness, thyroid disorders, liver disease, cancer, abnormal uterine bleeding (AUB) ;Not sensitive to any herb; Non-Smoking. Exclusion Criteria :Taking benzodiazepines, hypnotics, anti-coagulants such as aspirin, heparin and warfarin; Not receiving non-hormonal drugs to relieve menopausal symptoms such as clonidine and hormone therapy during the study; Sensitivity to medications used during the study; Not having any systemic disease; Not having tendency to continue the study.

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **123**

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

Ethical commitment of Tehran University of Medical Sciences

Street address

Sixth floor ,Central office, Ghods St, Keshavarz Blvd
City
Tehran
Postal code
Approval date
2013-07-27, 1392/05/05
Ethics committee reference number
92-01-28-21441-90058

Health conditions studied

1

Description of health condition studied

Hot flashes and sleep disorder in perimenopausal women

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Hot flushing

Timepoint

Baseline, 4 weeks and 8 weeks after

Method of measurement

Daily hot flash form

2

Description

Sleep disorder

Timepoint

Baseline, 4 weeks and 8 weeks after

Method of measurement

Pittsburgh Sleep Questionnaire Index

Secondary outcomes

1

Description

No

Timepoint

No

Method of measurement

No

Intervention groups

1

Description

Control group capsules containing starch, twice a day for 8 weeks

Category

Treatment - Drugs

2

Description

The first intervention group received 500 mg capsules of chamomile 2 times daily for 8 weeks

Category

Treatment - Drugs

3

Description

The second intervention group capsules of Hypericum 900 mg twice a day for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Women's Hospital

Full name of responsible person

Samaneh Hamzi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sciences vice chancellor for research- Tehran University of Medical Sciences

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Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran,

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

School of Nursing and Midwifery Tehran University of Medical Science

Full name of responsible person

Samaneh Hamzi

Position

M.Sc. student

Other areas of specialty/work

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Other areas of specialty/work**Street address**

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Web page address**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