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 andHypericum 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 questionnairesas 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

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Name of organization / entity

Iran university of medical sciences

Country

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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
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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
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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
Street address
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
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Full name of responsible person
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Person responsible for updating data

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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