Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of lemon balm, valerian and valerian/lemon balm on menopause women, sleep disorder in clients visited in health care clinics of Tehran university of Medical Science (2010)

Protocol summary

Summary

The objective of the study is to assess the effect of valerian root extract, lemon balm and combination of valerian/lemon balm on sleep disturbances in menopausal women referred to selected health centers affiliated to Tehran University of Medical Sciences. More than 400 volunteered menopausal women will be interviewed using Pittsburg Sleep Quality Index Questionnaire (PSQI). A total of 200 women of those who scored 5 or more will be invited to participate in the study and sign a written informed consent form. The participants will be randomly assigned into three intervention groups and a control group. The participants in the intervention groups will receive Sedamin, 530 mg capsule, Lemon Balm, 250 mg capsule, or Noragol (160 mg valerian and 80 mg lemon balm), twice daily for a month and those who are in the control group will receive placebo capsule, at the same dose as the intervention groups. Pittsburg Sleep Quality Index questionnaire score will be measured and compared for all participants before and one month after the intervention.

General information

Acronym

Effect of lemon balm, valerian and valerian/lemon balm on menopause womens

IRCT registration information

IRCT registration number: **IRCT201106302172N10**
Registration date: **2011-07-10, 1390/04/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-07-10, 1390/04/19

Registrant information

Name

Simin Taavoni

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lemon balm, valerian and valerian/lemon balm on menopause women, sleep disorder in clients visited in health care clinics of Tehran university of Medical Science (2010)

Public title

Effect of lemon balm, valerian and valerian/lemon balm on menopause women, sleep disorder in clients visited in health care clinics of Tehran university of Medical Science (2010)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Not having physical or psychological diseases which may cause sleep problems, Not to use tobacco, drugs or alcohol Exclusion criteria: Appearance of any physical illness and psychological disorder during the study period, Significant change in sleep conditions such as travel, shift work, etc. , Taking any additional medication during the study, Not taking the drug under investigation for more than 7 days during the study

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods Ave., Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2011-06-07, 1390/03/17

Ethics committee reference number

89-04-28-11933

Health conditions studied

1

Description of health condition studied

Sleep disorders

ICD-10 code

F51.0, F51

ICD-10 code description

Nonorganic sleep disorders

Primary outcomes

1

Description

Sleep dysfunction score

Timepoint

Before intervention and one month after intervention

Method of measurement

Pittsburg Sleep Quality Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Sedamin, 530 mg capsule, twice daily for one month

Category

Treatment - Drugs

2

Description

Intervention group 2: Lemon balm, 250 mg capsule, twice daily for one month

Category

Treatment - Drugs

3

Description

Intervention group 3: Noragol, 160 mg valerian and 80 mg lemon balm capsule, twice daily for one month

Category

Treatment - Drugs

4

Description

Control group: placebo, 50 mg capsule, twice daily for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeyni health center

Full name of responsible person

Shiva Eshtehardi, midwife

Street address
Saat Square, Old Karaj Road, Ghods City (Ghaleh Hassan Khan)
City
Qods

2

Recruitment center
Name of recruitment center
Emam Hossein health center
Full name of responsible person
Zahra Eskandarizade, MD, manager
Street address
Shahid Alami street, Azadi Square, Old Karaj Road, Ghods City (Ghaleh Hassan Khan)
City
Qods

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reasearch, Tehran University of Medical Sciences
Full name of responsible person
dr.fotoohi
Street address
Tehran University of Medical Sciences, Qods Ave., Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reasearch, 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
Nursing and Midwifery Faculty, Tehran University of Medical Sciences
Full name of responsible person
Simin Taavoni
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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