

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

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)

Phone

+98 21 8820 8161

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staavoni@iums.ac.ir

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,
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Web page address

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.,
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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

Position

M.Sc in Medical Education, M.Sc in Midwifery
Education, Academic Faculty Member & Resaercher

Other areas of specialty/work

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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
