

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 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)

##### Phone

+98 21 8820 8161

##### Email address

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, Ghods City (Ghaleh Hassan Khan)

**City**

Qods

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, 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 research, 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 & Researcher

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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*