

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jan 2020

### Effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388

#### Protocol summary

##### Summary

The objective of the study is to assess the effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388. More than 250 volunteered menopausal women will be interviewed using Pittsburg Sleep Quality Index Questionnaire (PSQI). About 100 of those who scored 5 or more will be invited to participate in the study and fill in a written consent form. Major inclusion and exclusion criteria include: • Not having physical and psychological diseases which may cause sleep problems • Not to use tobacco, drugs and alcohol • Appearance of any physical illness and psychological disorder while in study • 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. Subjects will be randomly divided into two 50 intervention and control groups. The intervention group will receive Sedamin, 530 mg capsule, twice daily for one month and the control group will receive placebo capsule, at the same dose as the intervention group. Pittsburg Sleep Quality Index questionnaire score will be measured and compared in the two groups before and one month after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903252172N4**

Registration date: **2010-06-29, 1389/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-06-29, 1389/04/08

##### 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

Iran University of Medical Sciences

##### Expected recruitment start date

2010-04-21, 1389/02/01

##### Expected recruitment end date

2010-05-22, 1389/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388

##### Public title

Effect of valerian root extract on sleep disturbances in menopausal women referred to selected health centers affiliated to Iran University of Medical Sciences 1388

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion and Exclusion criteria: • Not having physical and psychological diseases which may cause sleep problems • Not to use tobacco, drugs and alcohol • Appearance of any physical illness and psychological disorder while in study • 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

1-2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### 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

Nursing and Midwifery Faculty, Iran University of Medical Sciences

##### Street address

Valiasr street, after mirdamad, rashid yasemi street

##### City

Tehran

##### Postal code

19395/4798

##### Approval date

2010-03-12, 1388/12/21

##### Ethics committee reference number

1603057

## 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, Sedamin, 530 mg capsule, twice daily for one month

#### Category

Treatment - Drugs

### 2

#### Description

Control group, Starch, placebo capsule, twice daily for one month

#### Category

Placebo

## 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

Ghods

### 2

#### Recruitment center

##### Name of recruitment center

Emam Hoseyn 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

Ghods

## Sponsors / Funding sources

**1****Sponsor****Name of organization / entity**

Vice chancellor for reasearch, Iran University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Abass Motevalain, Dr. Mazyar Moradie Lakea

**Street address**

Vanak Highway, Next to Milad Hospital

**City**

Tehran

**Grant name****Grant code / Reference number**

854 ک

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

Yes

**Title of funding source**

Vice chancellor for reasearch, Iran 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, Iran 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****Street address**

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**Full name of responsible person**

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**Position**

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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**

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*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**

*empty*  
**Data Dictionary**  
*empty*

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