

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jan 2020

### The effect of valerian, lemon balm and combined valerian-lemon balm oral capsules on severity of menopausal symptoms in women aged 45-60

#### Protocol summary

##### Summary

This study is a clinical trial designed to determine the effect of valerian, lemon balm oral capsules and their combined consumption on the symptoms of menopause in women aged 45-60. 120 healthy postmenopausal volunteers referred to Imam Khomeini clinic and Imam Hussein clinic (30 persons in each group) eligible of entry criteria (cessation of menstruation for at least 12 months due to menopause, no history of allergy to valerian, lemon balm, and their combination, etc.) were enrolled into the study after completing informed consent.

Exclusion criteria were including any adverse effects during treatment including allergies to treatment capsules and no consumption of them to a maximum period of seven days or more per month of consumption, drug use, occurrence of any individual or family crises, and changes in diet and lifestyle such as changes to vegetarianism, health or addiction problems throughout research process. The subjects include three groups: treated with valerian, lemon balm, their combined form and the control group. The treatment group received 530 mg capsules of valerian (plant roots), or 250 mg Lemon Balm (plant leaves), or a combination of 160 mg valerian and 80 mg lemon balm, or 300 mg starch (controls) (capsules of the same form twice a day for eight weeks). The instruments of study consisted of demographic questionnaire, treatment registration forms and instrument of menopause evaluation criteria (physical, psychological and genitourinary dimensions) recorded and compared before treatment and then four and eight weeks after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201405312172N17**

Registration date: **2014-08-09, 1393/05/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-09, 1393/05/18

#### 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

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Vice Chancellor for Research, Iran University of Medical Sciences.

#### Expected recruitment start date

2014-07-06, 1393/04/15

#### Expected recruitment end date

2014-12-06, 1393/09/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of valerian, lemon balm and combined valerian-lemon balm oral capsules on severity of menopausal symptoms in women aged 45-60

#### Public title

The effect of valerian, lemon balm and combined valerian-lemon balm oral capsules on severity of menopausal symptoms in women

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: cessation of menstruation at least for 12 months due to menopause; no history of allergy to valerian, lemon balm and both of them; no history of drug use in the past two months, such as hormone

replacement therapy and psychotic drugs etc. Exclusion Criteria: any kind of side effects during treatment such as allergy to valerian, lemon balm and both of them; no taking of oral capsules valerian, lemon balm and both of them for a maximum period of seven days or more during any month of consumption; using any kind of drug throughout the study; occurrence of any individual or family crisis during research process; any kind of change in diet and life style such as changing to vegetarianism diet during the research process; any health problems or addictions throughout research process.

**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: **120**

**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**

Vice Chancellor for Research, Iran University of Medical Sciences

**Street address**

Vice Chancellor for Research, Iran University of Medical Sciences, Close to Milad Tower, Hemat Highway

**City**

Tehran

**Postal code****Approval date**

2014-07-11, 1393/04/20

**Ethics committee reference number**

102052

**Health conditions studied****1****Description of health condition studied**

Menopause Symptomes

**ICD-10 code**

N95.1

**ICD-10 code description**

Menopausal and female climacteric states

**2****Description of health condition studied**

menopause

**ICD-10 code**

N95.3

**ICD-10 code description**

States associated with artificial menopause

**Primary outcomes****1****Description**

Hot flush

**Timepoint**

Before intervention, at the end of first and second month after intervention

**Method of measurement**

Menopause Rating Scale Questionnaire

**2****Description**

Depression

**Timepoint**

Before intervention, at the end of first and second month after intervention

**Method of measurement**

Menopause Rating Scale Questionnaire

**3****Description**

Tachycardia

**Timepoint**

Before intervention, at the end of first and second month after intervention

**Method of measurement**

Menopause Rating Scale Questionnaire

**4****Description**

Insomnia

**Timepoint**

Before intervention, at the end of first and second month after intervention

**Method of measurement**

Menopause Rating Scale Questionnaire

**5****Description**

Anxiety  
**Timepoint**  
 Before intervention, at the end of first and second month after intervention  
**Method of measurement**  
 Menopause Rating Scale Questionnaire

## 6

**Description**  
 Vaginal dryness  
**Timepoint**  
 Before intervention, at the end of first and second month after intervention  
**Method of measurement**  
 Menopause Rating Scale Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
 Intervention 1: Oral use of 530 mg Valerian capsules, twice a day, for two months  
**Category**  
 Prevention

### 2

**Description**  
 Intervention 2: Oral use of 250 mg Lemon Balm capsules, twice a day, for two months  
**Category**  
 Prevention

### 3

**Description**  
 Intervention 3: Oral use of 80 mg Lemon Balm and 160 mg Valerian combined capsule, twice a day, for two months  
**Category**  
 Prevention

### 4

**Description**  
 Placebo Group: Oral use of 300 mg starch capsules, twice a day, for two months  
**Category**  
 Placebo

## Recruitment centers

### 1

**Recruitment center**  
 Name of recruitment center

Emam Khomeini Health Center  
**Full name of responsible person**  
 Dr.Bahram Rezaii  
**Street address**  
 Emam Khomeini Health Center, Saat Square,Ghods (Ghalee Hassan Khan) City, Karaj Former Road  
**City**  
 Tehran

### 2

**Recruitment center**  
**Name of recruitment center**  
 Emam Hossein Health Center  
**Full name of responsible person**  
 Dr.Mina Hosseini  
**Street address**  
 Emam Hosseini Health Center, Shahid Aalami Street, Ghods (Ghalee Hassan Khan) City, Karaj Former Road  
**City**  
 Tehran

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
 Faculty of Nursing and Midwifery, Tehran University of Medical Sciences  
**Full name of responsible person**  
 Dr Mohammad Ali Cheraghi  
**Street address**  
 Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Dr Mirkhany St. (N.East), Tohid Square  
**City**  
 Tehran  
**Grant name**  
 پایان نامه  
**Grant code / Reference number**  
 23441  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Faculty of Nursing and Midwifery, Tehran University of Medical Sciences  
**Proportion provided by this source**  
**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

### 2

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Iran University of Medical Sciences (Reserach proposal)

**Full name of responsible person**

Dr. Seied Ali Javad Mosavi

**Street address**

Vice Chancellor for Research, Iran University of Medical Science, Close to Milad Tower, Hemat Highway

**City**

Tehran

**Grant name**

طرح پژوهشی

**Grant code / Reference number**

23441

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

Yes

**Title of funding source**

Vice Chancellor for Research, Iran University of Medical Sciences (Reserach proposal)

**Proportion provided by this source****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 of Iran University of Medical Sciences

**Full name of responsible person**

Simin Taavoni

**Position**

Senior Lecturer, Head of Midwifery Continuing Education Office, Nursing and Midwifery Faculty, Iran

**Other areas of specialty/work****Street address**

3rd Floor, No.12, Nadjmabady St. Kazeroon St. Mirdamad Ave

**City**

Tehran

**Postal code**

1996713883

**Phone**

+98 21 8820 8161

**Fax****Email**

staavoni14@yahoo.com, staavoni@iums.ac.ir

**Web page address**

www.iums.ac.ir

**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

Faculty of Nursing and Midwifery, Iran University of Medical Sciences

**Full name of responsible person**

Simin Taavoni

**Position**

Senior Lecturer, Head of Midwifery Continuing Education Office, Nursing and Midwifery Faculty, Iran

**Other areas of specialty/work****Street address**

Nursing and Midwifery Faculty of Iran University of Medical, In opposition of Khatamol Anbia Hospital, Rashid Yasami St., Valiaasr Ave.

**City**

Tehran

**Postal code**

1996713883

**Phone**

+98 21 8820 8161

**Fax****Email**

staavoni14@yahoo.com, staavoni@iums.ac.ir

**Web page address**

www.iums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Nursing and Midwifery, Iran University of Medical Sciences

**Full name of responsible person**

Simin Taavoni

**Position**

Senior Lecturer, Head of Midwifery Continuing Education Office, Nursing and Midwifery Faculty, Iran

**Other areas of specialty/work****Street address**

Nursing and Midwifery Faculty of Iran University of Medical, In opposition of Khatamol Anbia Hospital, Rashid Yasami St., Valiaasr Ave.

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**Postal code**

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**Phone**

+98 21 8820 8161

**Fax****Email**

staavoni14@yahoo.com, staavoni@iums.ac.ir

**Web page address**

www.iums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

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**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*

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