

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)

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+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

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Position

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

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Full name of responsible person

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Position

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

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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**

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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
