Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

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

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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

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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

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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
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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

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Person responsible for updating data

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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