

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

On the consideration and comparison of Panjangosht (*Vitex agnus-castus*) and Maryamgoli (*Salvia officinalis*) effects on the osteogenic factors and physical and emotional symptoms in menopausal women

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

Objectives: In this study, alkaline phosphatase, osteocalcin, carboxy-terminal telopeptides of type I collagen, calcium, phosphorus, vitamin D, physical and psychological symptoms before and after treatment in vitex and sage extract group compared with the control group. **Design:** In this double-blind study of 100 postmenopausal women referred to hospital BMD Namazee(single core) by permutation block divided into three groups and blinding The idea is that participants with the contacts did not have the help of researcher Tablets black codes and put in jars to the researcher does not know what a pill each canister. **Setting and conduct:** First, personal information forms and a questionnaire about Menopause Rating Scale (MRS) and tests of osteogenic factors is performed and the above process is repeated after 3 months of intervention. **Inclusion criteria:** are osteopenic postmenopausal women who received calcium and vitamin D supplementation but do not receive other effective drugs on bone density. **Interventions:** the first intervention group is given, daily, one Agnugol tablets, 3.2- 4.8Mg(extract of VAC), the second group is given, daily, three Salvigol tablets, 100 Mg(*Salvia officinalis* extract), and the third group is given each day three placebo tablets.. Agnugol and Salvgl tablets are products Goldarou Company of Esfahan .main outcome: osteogenic factors - physical and mental symptoms.

Last update:

Update count: **0**

Registration date

2016-04-26, 1395/02/07

Registrant information

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Marzieh Akbarzadeh

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Shiraz University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

On the consideration and comparison of Panjangosht (*Vitex agnus-castus*) and Maryamgoli (*Salvia officinalis*)

General information

Acronym

comparison of Panjangosht and Maryamgoli effects on the osteogenic factors and physical and

IRCT registration information

IRCT registration number: **IRCT2015111713940N2**

Registration date: **2016-04-26, 1395/02/07**

effects on the osteogenic factors and physical and emotional symptoms in menopausal women

Public title

effect vitex and sage on osteogenic factors and physical and emotional symptoms in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :1) Menopausal women, 2) Women willing to cooperate in this study and presented their written consent form, 3) These women should not suffer from diseases related to liver, kidney, thyroid, parathyroid, intestine and bone..... in which they receive special medicines which affect the bone density, 4)They should not use any kinds of hormonal medicines, 5) Menopausal women who are osteopanic and receive supplementary Calcium and vitamin D, but they do not receive treatment with other with other effective hormonal medicines which affect the bone density (these medicines are mostly used by osteoprose patients), 6) They should not be sensitive to herbal medicines.
.Exclusion criteria:1) Allergic reaction to medicine, 2) Detection of a patient, during the study, who needs to use the medicine effective on bone density.

Age

No age limit

Gender

Female

Phase

N/A

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

Block permutation methods

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shiraz university of Medical Sciences

Street address

Shiraz - Zand Street - Next to the Red Crescent -

Sakhtmtn Central University - Class 7 - Research

City

Shiraz

Postal code

1978 -71345

Approval date

2016-01-24, 1394/11/04

Ethics committee reference number

IR.SUMS.REC.1394.185

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

2

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

osteogenic factors

Timepoint

At the beginning and end of the study

Method of measurement

Blood test

Secondary outcomes

1

Description

physical and emotional symptoms

Timepoint

At the beginning and end of the study

Method of measurement

the questionnaire about Menopause Rating Scale(MRS)

Intervention groups

1

Description

the first intervention group is given, daily, one Agnugol tablets, 3.2- 4.8 Mg for 3 months(product Goldarou Company of Esfahan)

Category

Treatment - Drugs

2

Description

the second intervention group is given, daily, three Salvigol tablets, 100 Mg for 3 months (product of Goldarou Company of Esfahan)

Category

Treatment - Drugs

3

Description

In control group is given each daily three placebo tablets for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazee hospital

Full name of responsible person

mohammadali tadayon

Street address

shiraz-Namazee hospital

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Shiraz University of Medical Sciences

Full name of responsible person

Dr.Masum masumpur

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City

shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice President of Research Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

marzieh akbarzadeh

Position

Master of Midwifery

Other areas of specialty/work

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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