

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of the combination of vitex agnus castus`s phytoestrogen and magnesium on serum alkaline phosphatase, osteocalcin, angiogenic factor and bone repair in 20-45-year-old wemen with long bone fracture.

Protocol summary

Summary

The purpose of current study is evaluation the effect of vitex agnus castus`s phytoestrogen and magnesium on serum alkaline phosphatase, osteocalcin, angiogenic factor and callus formation in wemen with traumatic long bone fracture. 64 women aged 20-45 years old with fracture of shaft of long bone were recruited from Chamran hospital. The women were randomly assigned into the four groups to receive vitex agnus castus supplements equal to 3.2-4.8 mg fruit dry extract; Magnesium supplements (250 mg); combination of vitex agnus castus and Magnesium supplements or placebo for 2 months. At baseline and at the end of the second month, biochemical and clinical evaluation will be measured. The primary outcome is increasing the index of alkaline phosphatase, osteocalcin, angiogenic factor and callus formation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092810955N1**

Registration date: **2012-10-29, 1391/08/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-29, 1391/08/08

Registrant information

Name

Mohammad Hasan Eftekhari

Name of organization / entity

School of health & nutrition, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1725 1002

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the combination of vitex agnus castus`s phytoestrogen and magnesium on serum alkaline phosphatase, osteocalcin, angiogenic factor and bone repair in 20-45-year-old wemen with long bone fracture.

Public title

The effect of the combination of vitex agnus castus`s phytoestrogen and magnesium on fracture healing.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women with fracture in long bone (femur, tibia, humerus, radius or ulna); 20-45-year-old.

Exclusion criteria: Pregnant or lactating; postmenopausal women; medications for any chronic disease (cancer, diabetes, CVD); use of medication known to affect bone

metabolism; use of herbal drug contain phytoestrogen, use of supplements (multivitamin-minerals,...), diuretics, hormonal drugs; Smoking; Alcohol consumption.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Blvd.

City

Shiraz

Postal code

1978-71345

Approval date

2012-09-16, 1391/06/26

Ethics committee reference number

CT-91-6235

Health conditions studied

1

Description of health condition studied

Fracture of shaft of femur

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

2

Description of health condition studied

Fracture of shaft of tibia

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

3

Description of health condition studied

Fracture of shaft of humerus

ICD-10 code

S42.3

ICD-10 code description

Fracture of shaft of humerus

4

Description of health condition studied

Fracture of shafts of both ulna and radius

ICD-10 code

S52.4

ICD-10 code description

Fracture of shafts of both ulna and radius

Primary outcomes

1

Description

Serum Alkaline phosphatase

Timepoint

Before and 2 months after intervention

Method of measurement

Calorimetry method

2

Description

Serum Osteocalcin

Timepoint

Before and 2 months after intervention

Method of measurement

ELISA kit

3

Description

Serum Vaso Endothelial Growth Factor

Timepoint

Before and 2 months after intervention

Method of measurement

ELISA kit

4

Description

Callus formation

Timepoint

Before and 2 months after intervention

Method of measurement

Radiographic Evidence

Secondary outcomes

empty

Intervention groups

1

Description

vitex agnus castus supplements intake is equivalent to 3.2-4.8 mg fruit dry extract per day, for 2 months

Category

Treatment - Drugs

2

Description

Magnesium supplements, 250 mg magnesium per day, for 2 months

Category

Treatment - Drugs

3

Description

placebo tablet, per day, for 2 months

Category

Placebo

4

Description

vitex agnus castus supplements intake is equivalent to 3.2-4.8 mg fruit dry extract per day, for 2 months and Magnesium supplements, 250 mg magnesium per day, for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital, Shiraz University of Medical Science

Full name of responsible person

Zahra Hasanzadeh Rostami

Street address

School of Health & Nutrition, Shiraz University of Medical Sciences

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahmodini

Street address

Central Medical Building, Zand Avenue

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

School of Health & Nutrition, Shiraz University of Medical Sciences

Full name of responsible person

Zahra Hasanzadeh Rostami

Position

MSc student of nutrition

Other areas of specialty/work

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PHD of nutrition, assistant professor of nutrition

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Other areas of specialty/work

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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

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty