Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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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