

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Assessment of the effect of Padzahr tablet on the turnover of bone formation in postmenopausal osteopenic women: A Randomized Double-Blind Placebo-Controlled Trial

Protocol summary

Study aim

Determination of the effectiveness of Padzahr tablet on the turnover of bone formation in postmenopausal osteopenic women

Design

Participants will be selected based on inclusion and exclusion criteria and divided into 2 groups, randomized, in the order of admission. Every group, based on the age, will be divided into 4 subgroups, 40-55, 50-55, 55-60 and 60-65. The first one of the similar age groups, will receive drug A and drug B will be given the second one and the others, by turns, will receive drug A or drug B. Intervention group will be ordered Padzahr tablet, 6 tablets daily, divided in 3 doses and control group will be ordered placebo tablet, the same way.

Settings and conduct

This research will be done in Akbarabadi hospital. Participants will be selected based on inclusion and exclusion criteria and divided into 2 groups, randomized, in the order of admission and every group, based on the age, will be divided into 4 subgroups. In order to assessment of the bone formation and bone resorption factors, blood sampling will be done, at the beginning of the study and after 3 months.

Participants/Inclusion and exclusion criteria

Osteopenic women Greater than 45 and under 65 years of age Osteopenia, based on WHO definition: T Score between -2.5 and -1 No history of allergy and anaphylaxis

Intervention groups

Intervention group: Osteopenic postmenopausal women, will be ordered Padzahr tablet: 6 tablets daily, divided in 3 doses. Control group: Osteopenic postmenopausal women, will be ordered placebo tablet: 6 tablets daily, divided in 3 doses.

Main outcome variables

OC BAP P1NP CTX-1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180710040406N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Shabnam Rafiee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4476 2837

Email address

sh-rafiee@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Padzahr tablet on the turnover of bone formation in postmenopausal osteopenic women: A Randomized Double-Blind Placebo-Controlled Trial

Public title

The effect of Padzahr tablet on Osteopenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Osteopenic postmenopausal women Greater than 45 and under 65 years of age Osteopenia, based on WHO definition: T Score between -2.5 and -1 No history of allergy and anaphylaxis

Exclusion criteria:

Use of Tobacco products, Alcohol and narcotic products History of chronic diseases, including Cancer, Cardiovascular diseases, Diabetes mellitus, Renal failure, Liver diseases, Systemic inflammatory diseases, Degenerative joint diseases, Rheumatologic disorders, Thalassemia, Primary hyperparathyroidism, Hyperthyroidism, Cushing's syndrome, Hypercalciuria, Hypogonadism Gastrointestinal diseases, including Crohn's disease, Ulcerative colitis, Celiac, Chronic diarrhea, under treatment gastric or duodenal ulcer, history of gastrointestinal bleeding History of drug consumption, affecting bone metabolism like Osteoporosis drugs, Diuretics, Thiazides, Anti convulsive drugs, Glucocorticoides and NSAIDES Motor disability and skeletal disorders except Osteopenia Untreated psychologic or neurologic diseases like Psychosis, Alzheimer and Parkinson Diseases History of bone diseases No tendency for randomization

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be selected based on inclusion and exclusion criteria and divided into 2 groups, randomized, in the order of admission. Every group, based on the age, will be divided into 4 subgroups, 40-55, 50-55, 55-60 and 60-65. The first one of the same age groups, will receive drug A and drug B will be given the second one and the others, by turns, will receive drug A or drug B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo will have codes and participants, Principal researcher, medical personnel, data collection authorities and statistical analyzer will not have information about drug and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

No. 27, Northern Sarparast street, West Taleghani Ave., Felestin square

City

Tehran

Province

Tehran

Postal code

1416663361

Approval date

2018-09-13, 1397/06/22

Ethics committee reference number

IR.TUMS.VCR.REC.1397.422

Health conditions studied**1****Description of health condition studied**

Osteopenia

ICD-10 code

M81.0

ICD-10 code description

Age-related osteoporosis without current pathological fracture

Primary outcomes**1****Description**

Turnover of bone formation based on Laboratory tests

Timepoint

Baseline and after 3 months

Method of measurement

ELISA laboratory tests

Secondary outcomes

1

Description

Plasma Osteocalcin (OC)

Timepoint

At the beginning of the study and 3 months after start of drug using

Method of measurement

Elisa Test

2

Description

Plasma Bone Alkaline Phosphatase (BAP)

Timepoint

At the beginning of the study and 3 months after start of drug using

Method of measurement

Elisa Test

3

Description

Plasma Procollagen Type 1 N-Terminal Propeptide (P1NP)

Timepoint

At the beginning of the study and 3 months after start of drug using

Method of measurement

Elisa Test

4

Description

Plasma C-terminal telopeptide (carboxy-terminal collagen crosslinks) (CTX)

Timepoint

At the beginning of the study and 3 months after start of drug using

Method of measurement

Elisa Test

Intervention groups

1

Description

Intervention group: Osteopenic postmenopausal women, will be ordered Padzahr tablet: 6 tablets daily, divided in 3 doses.

Category

Treatment - Drugs

2

Description

Control group: Osteopenic postmenopausal women, will be ordered placebo tablet: 6 tablets daily, divided in 3 doses.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi hospital

Full name of responsible person

Shabnam Rafiee

Street address

Molavi avenue

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Phone

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Fax

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Email

akbarabadihosp@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Niak company

Full name of responsible person

Dr. Hooman Bayat

Street address

Pasdaran Avenue

City

Gorgan

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Golestan

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49175/596

Phone

+98 17 3451 6192

Fax

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Email

Niak.pharmaceutical@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Niak company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shabnam Rafiee

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available