Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 recieve drug A and drug B will be given the second one and the others, by turns, will recieve 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 begining 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)

Phone
+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 choronic 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, Choronic 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, Northen 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
City
Tehran
Province
Tehran
Postal code
۱۱۶۸۷۴۳۵۱۴
Phone
+98 21 5560 6034
Fax
+98 21 5560 8012
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
Province
Golestan
Postal code
49175/596
Phone
+98 17 3451 6192
Fax
+98 17 3451 6194
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

Street address

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

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8897 4535

Email

Shara_514@yahoo.com

Person responsible for scientific 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

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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