

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of raloxifen on serum level of parathyroid hormone on osteoporotic menopausal women with stage 3 to 5 of chronic kidney disease.

Protocol summary

Summary

This is a clinical trial study that will be performed to demonstrate the effect of raloxifen on serum level of parathyroid hormone on osteoporotic menopausal women with stage 3 to 5 of chronic kidney. Inclusion criteria: longer than 1 years of menopause; patients under treatment hemodialysis or CKD patients with $GFR \leq 60$; age older than 35 years. Exclusion criteria were applied: previous HRT; venous occlusive disease; history of arteriovenous fistula thrombosis; cardiovascular disease, hepatic disease, or cancer; previous evidence of disease, other than chronic renal failure, that could affect bone metabolism; patients who had been recently treated with estrogen, progesterone, tibolone, corticosteroids, anticonvulsants, fluoride, bisphosphonates, or calcitonin; withdrawal of raloxifen for more than 4 weeks. After selecting the 60 cases, an informed consent will be obtained, the patients will be divided to two group that consist of 30 people and randomly matched by considering the level of parathyroid, age, count of hemodialysis and chronic kidney disease patients and during of menopause. The target parathyroid is described by KDOQI of 2007. Designing the study is double-blinded and involved placebo and drug group. In all patients, we will perform a baseline bone mineral density analysis and simultaneously evaluated different biochemical parameters, serum levels of total calcium, phosphorus, alkaline phosphatase, blood urea nitrogen, creatinine and level of parathyroid hormone. Bone densitometry and all laboratory tests will be reassessed after 6-months of therapy. The patients will be given 60mg Raloxifen or placebo and dosage of calcium and vitamin-D are as the KDOQI guideline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108167343N1**

Registration date: **2012-08-04, 1391/05/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-04, 1391/05/14

Registrant information

Name

Tahmineh Farbod Ara

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Science

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-03-05, 1391/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of raloxifen on serum level of parathyroid hormone on osteoporotic menopausal women with stage 3 to 5 of chronic kidney disease.

Public title

Effect of raloxifen on serum level of parathyroid hormone on osteoporotic menopausal women with stage 3 to 5 of chronic kidney disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: longer than 1 year that passed patient's menopause; patients under treatment in the hemodialysis units or CKD patients with GFR $\leq$ 60; age older than 35 years. The following exclusion criteria were applied: history of previous HRT; venous occlusive disease; previous history of arteriovenous fistula thrombosis; cardiovascular disease; hepatic disease; cancer; patients had previous evidence of disease, other than chronic renal failure, that could affect bone metabolism; patients who had been recently treated with estrogen, progesterone, tibolone, corticosteroids, anticonvulsants, fluoride, bisphosphonates, or calcitonin; withdrawal of raloxifen for more than 4 weeks were excluded from the study.

Age

From 35 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Arak University of Medical Science

Street address

Arak University of Medical Science, Basij Square

City

Arak

Postal code**Approval date**

2012-02-26, 1390/12/07

Ethics committee reference number

90-118-7

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

osteoporosis

ICD-10 code

m80.0

ICD-10 code description

Postmenopausal osteoporosis with pathological fracture

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

serum level of parathyroid hormone

Timepoint

baseline and 6 months after first sampling

Method of measurement

picogram/mililiter and by ELISA method

Secondary outcomes**1****Description**

serum calcium

Timepoint

baseline and 6 months after first sampling

Method of measurement

milligram/desiliter and photometry method

2**Description**

serum phosphorous

Timepoint

baseline nad 6 months after first sampling

Method of measurement

milligram/desiliter and photometry method

3**Description**

bone densitometry

Timepoint

baseline and 6 months after first sampling

Method of measurement

standard deviation(z-score and t-score) and DEXA method

4**Description**

fracture incidence

Timepoint

monthly after first sampling

Method of measurement

questionair and observational method

5

Description

serum alkaline phosphatase

Timepoint

baseline and 6 months after first sampling

Method of measurement

unit/liter and photometry method

Intervention groups

1

Description

At the first line in this study we do the bone densitometry in all patients in drug group to determine the severity of osteoporosis and also these laboratory tests as serum creatinine, serum Nitrogen-Urea, calcium, phosphorous and parathyroid hormone and alkaline-phosphates will be done, then reevaluated all these tests and bone densitometry after six months. We will initiate the study after first bone densitometry and laboratory tests. The drug group will take Raloxifen in dosage of 60mg daily. In all patients we prescribe calcium and vitamin D as KDOQI guideline, and monthly all patients will be visited by the researcher and asking them about probable adverse effect of drug, new fracture, and probable leaving the drug.

Category

Treatment - Drugs

2

Description

At the first line in this study we do the bone densitometry in all patients in placebo group to determine the severity of osteoporosis and also these laboratory tests as serum creatinine, serum Nitrogen-Urea, calcium, phosphorous and parathyroid hormone and alkaline-phosphates will be done, then reevaluated all these tests and bone densitometry after six months. We will initiate the study after first bone densitometry and laboratory tests. The placebo group will take a tablet daily, which is the same as Raloxifen. In all patients we prescribe calcium and vitamin D as KDOQI guideline, and monthly all all patients will be visited by the researcher and asking them about probable adverse effect of drug, new fracture, and probable leaving the placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis Center of Valiasr Hospital and
Nephrology clinic of of Amiralmomenin Hospital of
Arak

Full name of responsible person

Tahmineh Farbod Ara

Street address

Internal Medicine Department, Amiralmomenin
Medical Center, Arak University of Medical Sciences,
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Science

Full name of responsible person

Arak University of Medical Science, Deputy of
Education

Street address

Pardis Department, Arak University of Medical
Sciences, Basij Square

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Science

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

Arak University of Medical Science

Full name of responsible person

Tahmineh Farbod Ara

Position

Resident of Internal Medicine

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