Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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<=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 4weeks. 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

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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<=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 4weeks 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
millgram/desiliter and photometery method

2

Description
serum phosphorous
Timepoint
baseline nad 6 months after first sampling
Method of measurement
millgram/desiliter and photometery method

3

Description
bone densitometery
Timepoint
baseline and 6 months after first sampling
Method of measurement
standard deviation(z-score and t-score) and DEXA method

4

Description
fracture incidense
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 photometery 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, Basij Square
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