

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of raloxifen in post menopausal women with diabetic nephropathy

Protocol summary

Metabolic Diseases Research Center, Zanjan University of Medical Sciences

Summary

The objective of this study is to investigate 50 post-menopausal women with Type 2 diabetes and albuminuria (Albumin/Creatinine Ratio [ACR] \geq 30 μ g/mg) will be included in a 4-month, double-blind, placebo-controlled trial to receive either 60 mg raloxifene per day or placebo. Body mass index (BMI), blood pressure (BP), fasting blood glucose (FBS), HbA1C, lipid profiles, serum creatinine concentration (Cr), and random urine for ACR, will be measured for all the participants at the baseline and the end of the study.

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Scientific title

Effect of raloxifen in post menopausal women with diabetic nephropathy

Acronym

Public title

Effect of raloxifen on kidney function in post menopausal women with diabetic nephropathy

IRCT registration information

IRCT registration number: **IRCT138904151179N4**

Registration date: **2011-03-20, 1389/12/29**

Registration timing: **retrospective**

Purpose

Treatment

Last update:

Update count: **0**

Registration date

2011-03-20, 1389/12/29

Inclusion/Exclusion criteria

Inclusion Criteria : confirmed menopause (last period of the patient over the past year and FSH levels is more than 25mu/L, Age less than 70 years, confirmed albuminuria due to DM (ACR> 30mg/gr) Exclusion criteria: History of Treatment with estrogen or SERM in the past six months, a personal history of breast or Gynecologic cancer, History of thrombotic disorders, GFR less than 30 mL/min, hypertriglyceridemia over than 400 mg/dl, Active liver disease, intolerance to raloxifene or other Allergic reactions

Registrant information

Name

Faranak Sharifi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 1727 0815

Email address

zmdrc@zums.ac.ir

Age

From **45 years** old to **70 years** old

Gender

Female

Recruitment status

Recruitment complete

Phase

N/A

Groups that have been masked

No information

Funding source

Sample size

Target sample size: 50

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

Zanjan University of Medical Sciences Ethical Committee

Street address

Azadi Boulevard

City

Zanjan

Postal code

4515613191

Approval date

2009-10-18, 1388/07/26

Ethics committee reference number

4526/3-3/19

Health conditions studied

1

Description of health condition studied

Diabetic Nephropathy

ICD-10 code

E10, E11,

ICD-10 code description

Primary outcomes

1

Description

Albuminuria

Timepoint

at the beginning of the study and 4month after intervention

Method of measurement

Nephelometry

Secondary outcomes

1

Description

lipid profile(TG, Cholesterol, HDL-C)

Timepoint

at the beginning of the study and 4month after intervention

Method of measurement

Enzymatic methods

2

Description

Blood pressure

Timepoint

at the beginning of the study and 2&4 month after intervention

Method of measurement

standard methods checking for BP

3

Description

HbA1c

Timepoint

at the beginning of the study and 4 months after intervention

Method of measurement

lone exchange

Intervention groups

1

Description

placebo for 4 months

Category

Placebo

2

Description

Raloxifen tablets 60mg/daily for 4 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine Clinic of Zanjan, Vali -e-Asr Hospital

Full name of responsible person

Dr.Faranak Sharifi

Street address

Vali-e-Asr Hospital, Zanjan , Iran

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan Metabolic Diseases Research Center, Zanjan
University of Medical Sciences

Full name of responsible person

Dr. Alireza Biglari

Street address

Azadi Boulevard

City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan Metabolic Diseases Research Center, Zanjan
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**Name of organization / entity**

Zanjan Metabolic Diseases Research Center

Full name of responsible person

Dr. Faranak Sharifi

Position

Associate professor

Other areas of specialty/work**Street address**

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Full name of responsible person

Dr. Afagh Anjomshoaa

Position

MD

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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