

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of Bisphosphonate on the prevention of type 2 diabetes among Osteopenic menopause prediabetes women and Referred to Isfahan Endocrine and Metabolism Research Center.

Protocol summary

Summary

The aim of this Double Blind Randomized Controlled Trial, is to compare the effect of Bisphosphonate on blood glucose, sensitivity index and insulin premonition in Osteopenic menopause women in 2016-2017. The RCT will be carried out in the Endocrine and Metabolism Research Centre of Isfahan University of Medical Sciences and Hope Hospital Bone Densitometry Center (BMD). Among all patients who referred to Hope Hospital for bone densitometry, 60 eligible Osteopenic and prediabetes and menopause patients will be recruited and randomly allocated to intervention and control groups. The trial group will receive 70 mg Alendronate and control group placebo weekly for 3 months. The outcomes, blood Glucose, sensitivity index and insulin resistance will be measured at the baseline and at the end of follow up and compared between trial and control group. Inclusion and exclusion criteria Inclusion criteria Prediabetes and menopause female patients who are resistant to insulin at age between 45 to 60 will be included if fulfilling the following two criteria: Osteopenia based on bone density measured by DAX machine Hologic 2008 model; Written consent by the patient to participate in the study obtained at the baseline Exclusion criteria Patients fulfilling any of the following criteria will be excluded from the study; Failure to use vitamin of OTC or trace element; Patients who do not like to continue with the study for any reason; Patients who take drugs that affect metabolism of glucose; The Osteoporotic patient; Patients with kidney failure problem.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101530309N1**

Registration date: **2016-12-31, 1395/10/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-31, 1395/10/11

Registrant information

Name

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Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Bisphosphonate on the prevention of type 2 diabetes among Osteopenic menopause prediabetes women and Referred to Isfahan Endocrine and Metabolism Research Center.

Public title

Comparison of the effect of Bisphosphonate on the prevention of type 2 diabetes among Osteopenic menopause prediabetes women and Referred to Isfahan Endocrine and Metabolism Research Center.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion and exclusion criteria
Inclusion criteria
Prediabetes and menopause female patients who are resistant to insulin at age between 45 to 60 will be included if fulfilling the following two criteria: Osteopenia based on bone density measured by DAX machine Hologic 2008 model; Written consent by the patient to participate in the study obtained at the baseline
Exclusion criteria
Patients fulfilling any of the following criteria will be excluded from the study; Failure to use vitamin of OTC or trace element; Patients who do not like to continue with the study for any reason; Patients who take drugs that affect metabolism of glucose; The Osteoporotic patient; Patients with kidney failure problem.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

2-3

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

Ethics Committee Isfahan University of Medical Sciences

Street address

No.4, Hezar jarib St, Isfahan

City

Isfahan

Postal code

8187698191

Approval date

2016-06-09, 1395/03/20

Ethics committee reference number

lr.mui.rec.1395.3.292

Health conditions studied

1

Description of health condition studied

Prediabetes

ICD-10 code

R73, N95,

ICD-10 code description

Impaired glucose tolerance, Menopausal and other perimenopausal disorders, Postmenopausal osteoporosis

Primary outcomes

1

Description

25 OH D3

Timepoint

Before and three months after the study

Method of measurement

Blood test

2

Description

Plasma glucose, Insulin Sensitivity and Insulin Resistance, HbA1C

Timepoint

Before and three months after the study

Method of measurement

Blood test

3

Description

Lipid Profile TG - Total Cholesterol LDL-HDL

Timepoint

Before and three months after the study

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Randomisation and blinding: Patients who are screened,

signed the consent form, and fulfilled inclusion criteria and meet no exclusion criteria will be randomised using a sealed envelope to either 70 mg Alendronate (trial group) or placebo (control group). The randomisation and preparation of sealed envelopes are performed by an independent party at the Hope Hospital. Randomisation will be performed using a computerised random number generator. The research team is blinded to block size. Measurements of, blood Glucose, sensitivity index and insulin resistance will be performed by a member of the research team who is blinded to the treatment allocation at the baseline and at the end of follow up. Control group: Thirty patients whom allocated to placebo group, will be treated as trial group. They will receive placebo tablet exactly the same size and colour of Alendronate tablet without substance with therapeutic effect. Control group patients will also be asked to take one tablet once a week for 12 weeks in the morning while fasting with one glass of water and no lying down, at least, an hour after taking the tablet. They will receive information on all potential side effects and how to cope with if any side effect happened.

Category

Treatment - Drugs

2**Description**

Randomisation and blinding: Patients who are screened, signed the consent form, and fulfilled inclusion criteria and meet no exclusion criteria will be randomised using a sealed envelope to either 70 mg Alendronate (trial group) or placebo (control group). The randomisation and preparation of sealed envelopes are performed by an independent party at the Hope Hospital. Randomisation will be performed using a computerised random number generator. The research team is blinded to block size. Measurements of, blood Glucose, sensitivity index and insulin resistance will be performed by a member of the research team who is blinded to the treatment allocation at the baseline and at the end of follow up. Trial group: Both trial and control group will be asked to take one Alendronate tablets is a bisphosphonate drug, it is chemically related to inorganic pyrophosphate, the endogenous regulator of bone turnover, once a week for 12 weeks in the morning while fasting with one glass of water and no lying down, at least, an hour after taking the tablet. All patients will be given information on all potential side effects and how to cope with if any side effect happened.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Endocrine and Metabolism Research Center,
Isfahan University of Medical Sciences

Full name of responsible person

Dr.Kachuie

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Isfahan University of
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Full name of responsible person

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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

Vice chancellor for research, Isfahan 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**

Isfahan Endocrine and Metabolism Research Center,
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Full name of responsible person

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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