

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Metformin and placebo effects on TSH and thyroid volume in patients with pre-diabetes

Protocol summary

Summary

The people with pre-diabetes are insulin resistant. This situation can increased the risk of diabetes mellitus and cardiovascular diseases. On the other hand may affects thyroid function or its size and so may cause thyroid nodule. In the present study we are going to investigate the effects of metformin on the thyroid gland (volume and function) in pre-diabetic patients. Our study is a double blind placebo- control clinical trial. The participants are selected from the first degree relatives of type-2 diabetes mellitus who are screened during a diabetes primary preventive program in Isfahan Endocrine and Metabolism Research Center. The patients target sample size will be 72 patients. The patients are randomly allocated to the 2 treatment groups. The first group will receive metformin and the second, placebo for 3 consequent months. After taking history and physical examination, blood sample will be taken and stored in -20 °C in Isfahan Endocrine and Metabolism Research Center lab until, laboratory assay will be done(CBC diff- Creatinin-AST-ALT-ALKP-T3-T4-TSH-T3RU-AntiThyroid Peroxidase Antibody- Anti Thyroglobulin Antibody -Triglyceride -Cholesterol -HDL Cholesterol -LDL Cholesterols- Insulin- HbA1C-FBS). Thyroid ultrasound will be done before and 3 months after staring metformin or placebo. The patients will be seen every month and drug adherence was assessed by pill count. All the laboratory tests will be repeated after 3 months of receiving metformin or placebo. All patients with thyroid nodules >1 cm were offered to undergo fine needle aspiration biopsy (FNAB).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121215765N1**

Registration date: **2014-05-29, 1393/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-29, 1393/03/08

Registrant information

Name

Mozhgan Karimifar

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan Endocrine and Metabolism Research Center,
Raha Pharmaceutical Company

Expected recruitment start date

2013-04-01, 1392/01/12

Expected recruitment end date

2014-03-16, 1392/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Metformin and placebo effects on TSH and thyroid volume in patients with pre-diabetes

Public title

Metformin and placebo effects on TSH and thyroid volume in patients with pre-diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :patients with pre-diabetes [Impaired fasting plasma glucose (100 to 125 mg/dl) or impaired glucose tolerance (IGT) (2-h PG OGTT values of 140-199 mg/dL and having 18 to 65 years old] were initially included. Exclusion criteria: Those patients with thyroid malignancy or any other malignancy; previous-thyroxin suppression therapy at any time; obesity due to endocrine disease; Pregnancy and lactation; renal failure or liver failure; neurological or psychological disorders (depression, epilepsy, schizophrenia); heart failure; hypothyroidism or hyperthyroidism; smoking and finally iodinated contrast material exposure in the previous 6 months ago all were excluded from the study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **76**

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Avenu,Isfahan, Iran

City

Isfahan

Postal code

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

392299

Health conditions studied

1

Description of health condition studied

Thyroid gland

ICD-10 code

E00-E07,E0

ICD-10 code description

Disorders of thyroid gland

2

Description of health condition studied

Prediabetes

ICD-10 code

R73.0

ICD-10 code description

Impaired glucose tolerance

Primary outcomes

1

Description

Thyroid Stimulating Hormone

Timepoint

Baseline and 3 months later

Method of measurement

TSH : were performed using immunoassay system by an automated analyzer Siemens 2010 (ADVIA Centaur CP Immunoassay System).

2

Description

Thyroid volume

Timepoint

Before and after 3 months treatment

Method of measurement

Thyroid ultrasonography was performed by single physician, who was unaware of the patients' any clinical conditions, using a 7 - 9 MHz linear probe (Logiq 500 Pro, GE Medical Systems, WI, USA).

Secondary outcomes

1

Description

Thyroid Nodule

Timepoint

Baseline and 3 months later

Method of measurement

Thyroid ultrasound by logic 500 general electric probe 7-9

2

Description

IR=Homeostasis Model Assessment Of Insulin Resistance

Timepoint

Baseline and 3 months later

Method of measurement

HOMA-IR = { Insulin(mU/L) × Fasting Blood

glucose(mmol/L)}÷22.5

Intervention groups

1

Description

One group will receive placebo with a secret code. (Subjects were instructed to take 1 tablet 500 mg placebo daily. But in the 1st week, subjects were instructed to take 2 tablet 500 mg daily, if subjects tolerated the dose-escalation protocol without significant side effects, the daily dose was increased to 1500 mg daily).

Category

Placebo

2

Description

The other group will receive metformin with a secret code. (Subjects were instructed to take 1 tablet 500 mg Metformin daily. But in the 1st week, subjects were instructed to take 2 tablet 500 mg daily, if subjects tolerated the dose-escalation protocol without significant side effects, the daily dose was increased to 1500 mg daily).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Mozhgan Karimifard, Internist, Fellowship of Endocrinology and metabolism

Street address

Isfahan Endocrine and Metabolism Research Center, Khorram avenue, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Ashraf Aminoroaya MD-Professor of Internal Medicine and Endocrinology-Head of Endocrinology Department

Street address

Isfahan Endocrine and Metabolism Research Center, Khorram Street, Isfahan, Iran

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Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan Endocrine and Metabolism Research Center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Raha Pharmaceutical Company

Full name of responsible person

Mohammadali Mansouri Tehrani - Director of sales and marketing of Raha pharmaceutical company

Street address

Unit 11, Shahrak Sanaty Softe, kilometer Seven, Shiraz road.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Raha Pharmaceutical Company

Proportion provided by this source

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

Full name of responsible person

Mozhgan karimifar

Position

Fellowship of endocrinology

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