

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of Metformin on thyroid function in patients with sub-clinical Hypothyroidism

Protocol summary

Summary

The aim of this clinical trial was evaluation of the effect of Metformin on reduction of Tirotopine level in patients with Subclinical hypothyroidism. Inclusion criteria included, do not use Thyrotropin-lowering drugs and Thyrotropin level between 5-10 miu/L. Exclusion criteria included lack of consent, renal insufficiency or GFR less than 50, Intolerance of oral Metformin and Pregnancy or post partum state. This study that performed on patients with Subclinical hypothyroidism. Sixty patients evaluated in two intervention and control groups. In intervention group, Tablet metformin 1 gr every 12 hours for 3 months and in the control group, Placebo will be prescribed. Thyroid function tests Will be measured before and after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304073565N8**

Registration date: **2015-07-05, 1394/04/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-05, 1394/04/14

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Bone disease health center, Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Metformin on thyroid function in patients with sub-clinical Hypothyroidism

Public title

Evaluation of the effect of Metformin on thyroid function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having metabolic syndrome criteria; Thyrotropin levels between 5 to 10 miu / L Exclusion criteria: lack of consent; Renal insufficiency or GFR less than 50; Pregnancy

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: 60

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street addressTabriz University of Medical Sciences, Daneshgah Sq
Tabriz Eastern Azarbyjan Iran, Islamic Republic Of**City**

Tabriz

Postal code**Approval date**

2015-01-10, 1393/10/20

Ethics committee reference number

93152

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

Subclinical hypothyroidism

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

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

TSH Level

Timepoint

Before and 3 months after study

Method of measurement

Elisa method

2**Description**

T4 Level

Timepoint

Before and 3 months after study

Method of measurement

Elisa method

Secondary outcomes

empty

Intervention groups**1****Description**

In intervention group: Tablet Metformin 1gr each 12 hours for 3 months

Category

Treatment - Drugs

2**Description**

In control group: Placebo each 12 hours for 3 months

Category

Treatment - Drugs

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

Endocrinology Clinic of Imam Reza Hospital

Full name of responsible person

Dr Zynolabedin Nurcheshmeh

Street addressImam Reza medical research and training hospital,
Daneshgah Ave, Tabriz**City**

Tabriz

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

Bone Research Center

Full name of responsible person

Dr. Amir Bahrami

Street addressBone Research Center, Imam Reza medical research
and training hospital, Daneshgah Ave, Tabriz**City**

Tabriz

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

Yes

Title of funding source

Bone Research Center
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
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Person responsible for updating data

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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