

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of levothyroxine in comparison with placebo on serum osteocalcin levels in patients with subclinical hypothyroidism

Protocol summary

Study aim

Determining the effect of levothyroxine in comparison with placebo on serum osteocalcin levels in patients with subclinical hypothyroidism and its association with metabolic syndrome

Design

In this study, 30 patients with subclinical hypothyroidism who are admitted to the endocrinology clinic are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

In this study, 30 patients with Subclinical hypothyroidism who have been admitted to study at the Endocrine clinic are selected. Participants were randomly divided into two groups of intervention and control (placebo) and serum levels of Osteocalcine were measured and compared in two groups. Medicines were prepared in two groups a and b (levothyroxine and placebo) and a specialist according to a randomisation table By the computer, the patients will be given medications. Both patient and specialist groups are blinded.

Participants/Inclusion and exclusion criteria

Admission criteria: People aged 20-40 years old referred to the endocrinology clinic; SCH have indications of treatment. Exit criteria: A history of hypothyroidism, Treated with antithyroid drugs , Hyperparathyroid, Acromegaly, Medicines causing thyroid disorder: Interferon, Tyrosine kinase, cortisone , ocp and Drugs that affect insulin levels.

Intervention groups

Levothyroxine recipients placebo recipients

Main outcome variables

Serum levels of osteocalcine

General information

Reason for update

Acronym

SCH

IRCT registration information

IRCT registration number: **IRCT20171129037677N1**

Registration date: **2018-04-27, 1397/02/07**

Registration timing: **retrospective**

Last update: **2018-04-27, 1397/02/07**

Update count: **0**

Registration date

2018-04-27, 1397/02/07

Registrant information

Name

reihaneh rezaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4234 5674

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of levothyroxine in comparison with placebo on serum osteocalcin levels in patients with subclinical hypothyroidism

Public title

The effect of levothyroxine in subclinical hypothyroidism

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

People aged 20-40 years old referred to the endocrinology clinic Subclinical hypothyroidism have indications of treatment(Tsh5-15 andT3-T4 in normal range)

Exclusion criteria:

History of hypothyroidism Treated with antithyroid drugs Metabolic bone disorder Hypoparathyroid and hyperparathyroid Acromegaly Drugs that cause thyroid dysfunction: Interferon-tyrosine kinase-cortisone and ocp Drugs that affect insulin levels

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this work, using a simple randomization model (computer randomization method), we will rank each referral in the intervention or control group based on the order of the randomization table. Statistical software is a random tool. The randomization unit is individual. Levothyroxine and placebo will be placed in the numbered envelopes, each patient will be given an open envelope at the clinic and given the medicine..

Blinding (investigator's opinion)

Double blinded

Blinding description

Based on the randomization table that will be provided by the computer, levothyroxine and placebo will be placed in the numbered envelopes; each patient will be given an open envelope for each patient and the medication will be given to him. A list of how the patient is assigned to one of the project partners to inform him about the grouping of patients. The patient will not be aware of the grouping. During this 60 day period (treatment period), at least 1 time a month, contact persons are contacted to ensure that patients are taking drugs. Patients are also asked to do the test again at week eight after starting treatment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Emam Reza hospital.Bahar street

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Mashhad

Province

Razavi Khorasan

Postal code

91379-13131

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

IR.MUMS.fm.REC.1395.472

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**

Serum osteocalcin levels

Timepoint

Measurement of osteocalcin levels before the intervention and two months later

Method of measurement

Serum level evaluation

Secondary outcomes

empty

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

Intervention group: Levothyroxine receptor

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Reihaneh Rezaee

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

دکتر محسن تفقدي

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مشهد-خیابان دانشگاه- جنب سینما هویزه- دانشگاه علوم پزشکی
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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoud Mohebbi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available