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

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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
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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 مشهد- معاونت پژوهش و فناوری دانشگاه
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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

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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