Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparison of oxidant and anti oxidant level after levothyroxin therapy between subclinical hypothyroid patients and normal group

Protocol summary

Study aim
The effect of levothyroxine therapy on oxidant-antioxidant balance and CRP in patients with subclinical hypothyroidism
Design
double-blind, randomized clinical trial with control group, parallel groups, phase 3 on 30 patients. To randomize, random sequence production software was used as a block.
Settings and conduct
double-blind clinical trial -Arash Hospital
Participants/Inclusion and exclusion criteria
Patients with confirmed SCH and age between 17 and 42 years were included in the study and those with pregnancy or planning for pregnancy, history of diabetes and cardiovascular, renal and hepatic diseases, smoking and alcohol use, as well as those taking levothyroxine, lipid-lowering agents, antihypertensive drugs and those taking vitamin supplements effective on OS, were excluded from the study. Subclinical hypothyroidism was defined as TSH level equal or greater than 5 Miu/l but below 10 mg/dl with normal thyroxin (T4) level (5-12µg/dl).
Intervention groups
Iran Hormone Pharmaceutical Company used 50 micrograms of levothyroxine daily in the intervention group and placebo drug prepared by the Faculty of Pharmacy of Tehran University of Medical Sciences was used in the control group.
Main outcome variables
Oxidant and antioxidant balance hs-CRP

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20121001010980N4**
Registration date: **2020-05-28, 1399/03/08**
Registration timing: **retrospective**

Last update: **2020-05-28, 1399/03/08**
Update count: **0**
Registration date
2020-05-28, 1399/03/08

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-04-04, 1395/01/16
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
2016-04-04, 1395/01/16
Actual recruitment end date
2018-09-22, 1397/06/31
Trial completion date
2018-09-22, 1397/06/31

Scientific title
comparison of oxidant and anti oxidant level after levothyroxin therapy between subclinical hypothyroid patients and normal group

Public title
Evaluation of Levothyroxin therapy on Oxidant and anti

Oxidant level in subclinical hypothyroid patients

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

age=17-42 5<=TSH>=10 NORMAL TotalT4

Exclusion criteria:

Smoking alcohol consumption Pregnancy and pregnancy intent Sodium levothyroxine consumption lipid lowering drugs Anti hypertensive drugs Taking vitamin supplements that affect the state of oxidative stress History of diabetes Mellitus - History of cardiovascular disease History of liver disease History of kidney disease

Age

From **17 years** old to **42 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

serum sample

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

serum sample

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is block randomization. The unit of randomization is the individual. The randomization tool is statistical software and the method of making random sequences obtained by the software is done According to the table, coded envelopes with a random sequence were used to allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principal investigators, data collection authorities, and those who assess the outcome and patients (after obtaining written consent) are blinded to which patient was in the drug group and which patient was in the placebo group. The blinding was done using small envelopes containing medicine or placebo on which the code A or B was written based on a random table.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam khomeini hospital

Street address

Keshavarz Blv-Imam Khomeni Hospital

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.3665

Health conditions studied

1

Description of health condition studied

subclinical hypothyroidism

ICD-10 code

E03.8

ICD-10 code description

Other specified hypothyroidism

Primary outcomes

1

Description

Oxidant-Antioxidant balance

Timepoint

before intervention and 12 weeks after levothyroxin therapy

Method of measurement

serum sample.By the method of measuring prooxidant-antioxidant balance.Measurement of light spectrum by Eliza reader

2

Description

hs-CRP

Timepoint

before intervention and 12 weeks after levothyroxin

Method of measurement

serum sample.Immunoturbidometry assay with commercial kit.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Levothyroxine tablet treatment intervention group with 50 micrograms once daily orally for 3 months (Iran Hormone Company 2).
Category
Treatment - Drugs

2

Description
Control group: In this group placebo , made by the Faculty of Pharmacy of Tehran University of Medical Sciences, were given orally administered once a day for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash hospital
Full name of responsible person
Nooshin Shirzad
Street address
Eastern 162th St.,Baghdarnia st.,Resalat Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Endocrinology and Metabolism Research Institute
Full name of responsible person
Nooshin Shirzad
Street address
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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
Endocrinology and Metabolism Research Institute
Proportion provided by this source
30
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
Tehran University of Medical Sciences
Full name of responsible person
Nooshin Shirzad
Position
Assiciate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
main outcome data
When the data will become available and for how long
6 months after publication
To whom data/document is available
Researchers working in scientific institutes
Under which criteria data/document could be used
Use study variables for other research in this area
From where data/document is obtainable
Nooshin Shirzad nshirzad11@gmail.com
What processes are involved for a request to access data/document
Request through the Scientific Institute
Comments