

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Nooshin Shirzad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

nshirzad@tums.ac.ir

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 science

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

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3284

Email

hosp_arash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute

Full name of responsible person

Nooshin Shirzad

Street address

Endocrine and metabic research institute-Aleahmad Hwy

City

Tehran

Province

Tehran

Postal code

1411713137

Phone

+98 21 8863 1298

Email

emrc@tums.ac.ir

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

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Imam Khomeini Hospital Complex, Tohid Squire

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

0098 21 ۶۱۱۹۰

Email

nshirzad11@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nooshin Shirzad

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrine disease

Street address

Imam Khomeini Hospital Complex, Tohid Square

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

00982161190

Email

nshirzad11@gmail.com

00982161190

Email

nshirzad11@gmail.com

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Nooshin Shirzad

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrine disease

Street address

Imam Khomeini Hospital Complex, Tohid Square

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone