

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of sodium levothyroxine on Electrocardiography findings(QTc & QTd) of subclinical hypothyroidism patients

Protocol summary

Study aim

To determine the effect of levothyroxine on Electrocardiographic findings(QTc & QTd) in patients with subclinical hypothyroidism

Design

Two arms parallel-group randomized trial with blinded and outcome assessment of 200 patients that followed for 3 months.

Settings and conduct

Patients with subclinical hypothyroidism referred to Mahdiah Special Clinic in Kermanshah will be invited to participate in the study. The study will be designed to be double-blind, the participants in the study and the physician responsible for electrocardiography will not be aware of the assigned treatments. The levothyroxine sodium (50 M) produced by Iran Hormone Pharmaceutical Company will be used in the study. The placebo is also produced by the same company and will be similar in terms of shape, packaging, color size and smell.

Participants/Inclusion and exclusion criteria

Patients with subclinical hypothyroidism who have a QTc longer than 460 milliseconds. Inclusion criteria: 1- TSH level more than 5 nanograms per deciliter and normal thyroid hormones 2- QTc level more than 460 milliseconds 3- Absence of heart disease 4- Age range 20-50 years and exclusion criteria: 1- Pregnancy or hormonal disorder 2- Taking drugs that affect the QTc interval

Intervention groups

The treatment group will receive 50 micrograms of levothyroxine sodium daily for 3 months and the control group will receive placebo daily for the same period.

Main outcome variables

QTcorrection & QTdispersion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210331050794N1**
Registration date: **2021-05-15, 1400/02/25**
Registration timing: **prospective**

Last update: **2021-05-15, 1400/02/25**

Update count: **0**

Registration date

2021-05-15, 1400/02/25

Registrant information

Name

Asadollah Amiripour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 0252

Email address

asadamiri1351@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sodium levothyroxine on Electrocardiography findings(QTc & QTd) of subclinical hypothyroidism patients

Public title

Effect of sodium levothyroxine on Electrocardiographic findings (QTc and QTd)

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

TSH levels greater than 5 nanograms per deciliter and normal thyroid hormones QTc greater than 460 ms absence of heart disease Age range 20-50 years

Exclusion criteria:

Pregnancy or hormonal disorder Taking drugs that affect the QTc interval

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent using block randomization and allocation ratio 1: 1, participants will be randomly divided into two study groups. A combination of 4 and 6 random blocks generated by the sealed envelope website, <https://www.sealedenvelope.com>, will be used to assign intervention to participants. On this website, after setting the seed, we will generate a list of 200 numbers to assign participants into two groups, A and B. Then, using the mentioned list, patients were divided into designated groups. Once participants have consented, each participant will be given a study identification number at the study site. In order to conceal the randomization process, the allocation sequence is given to the person in charge of randomization in the clinic in a sealed form using envelopes containing the number of numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be designed to be double-blind, the participants in the study and the physician responsible for electrocardiography will not be aware of the assigned treatments. The levothyroxine sodium (50 M) produced by Iran Hormone Pharmaceutical Company will be used in the study. The placebo is also produced by the same company and will be similar in terms of shape, packaging, color size and smell.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kermanshah University of Medical Sciences

Street address

Imam Ali Cardiovascular Hospital, Kermanshah University of Medical Sciences, Shahid Beheshti Street

City

Kermanshah

Province

Kermanshah

Postal code

6715847145

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.KUMS.REC.1399.1032

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**

Change in QTc&QTd interval

Timepoint

QTc & QTd measurements will be performed before the intervention and 3 months after receiving the intervention.

Method of measurement

QTc & QTd measurements will be performed using electrocardiography.

Secondary outcomes

empty

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

Intervention group: will receive 50 micrograms of levothyroxine sodium daily for 3 months .

Category

Prevention

2

Description

Control group: Includes patients with subclinical hypothyroidism with a TSH of 5-10 ng / dL who will receive a placebo daily for 3 months. The duration, method of use and follow-up of control group will be completely similar to the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mahdieh Special Clinic in Kermanshah

Full name of responsible person

Asadollah Amiripour

Street address

Imam Ali Cardiovascular Hospital, Kermanshah
University of Medical Sciences, Shahid Beheshti
Street

City

Kermanshah

Province

Kermanshah

Postal code

6715847145

Phone

+98 83 3837 0252

Email

asadamiri1351@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khodarahmi

Street address

No. 2 Central Building, Kermanshah University of
Medical Sciences, Shahid Beheshti Street,
Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3838 6835

Email

research_it@kums.ac.ir

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

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Asadollah Amiripour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Ali Cardiovascular Hospital, Kermanshah
University of Medical Sciences, Shahid Beheshti
Street

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3838 6835

Email

asadamiri1351@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Asadollah Amiripour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Ali Cardiovascular Hospital, Kermanshah

University of Medical Sciences, Shahid Beheshti
Street

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3837 0252

Email

asadamiri1351@yahoo.com

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3837 0252

Email

asadamiri1351@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Asadollah Amiripour

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Ali Cardiovascular Hospital, Kermanshah
University of Medical Sciences, Shahid Beheshti
Street

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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