Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Mahdieh 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

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

City
Kermanshah

Province
Kermanshah

Postal code
6714673159

Phone
+98 83 3837 0252

Email
asadamiri1351@yahoo.com

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