

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of levothyroxine therapy on sex hormone levels in women with subclinical Hypothyroidism.

Protocol summary

Study aim

Determination of the effect of levothyroxine therapy on sex hormones in women with subclinical hypothyroidism

Design

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct

This study was conducted to evaluate the effect of levothyroxine therapy on the level of sex hormones in women with subclinical hypothyroidism in the clinic of Vaseji Hospital in Sabzevar. Clinical observant and participants will be unaware of how they are grouped. Patients will be randomized in the intervention group (levothyroxine) and in the control (placebo). The response to treatment is evaluated by ELISA at the end of the second month after the intervention for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 17-40 years with TSH above the maximum normal laboratory range and less than 10 and also T3, T4 normal. Exclusion criteria: Irregular ovarian cycles (irregular menstruation) Pregnancy, breastfeeding, hypothalamic amenorrhoea, known pituitary diseases, and early menopause. The history of ovarian surgery, polycystic ovary syndrome (PCOS), and the use of hormonal medications History of levothyroxine tablets in the last two months
Dissatisfaction patients to participate in the study.

Intervention groups

Intervention group: Patients in this group were treated with levothyroxine (50 micrograms daily and 5 days a week fasting) with the aim of Euthyroidism. Control group: Patients in this group were treated with placebo for two months (fasting 5 days a week).

Main outcome variables

Determination of Estrogen and Progesterone levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N6**

Registration date: **2019-01-23, 1397/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

Registration date

2019-01-23, 1397/11/03

Registrant information

Name

Mohammad Sahebkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-11, 1397/10/21

Expected recruitment end date

2019-04-10, 1398/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of levothyroxine therapy on sex hormone levels in women with subclinical Hypothyroidism.

Public title

Investigating the effect of levothyroxine therapy on sex hormone levels

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 17-40 years with TSH above the maximum normal laboratory range and less than 10 and also T3, T4 normal.

Exclusion criteria:

Irregular ovarian cycles (irregular menstruation)
Pregnancy, breastfeeding, hypothalamic amenorrhoea, known pituitary diseases, and early menopause. The history of ovarian surgery, polycystic ovary syndrome (PCOS), and the use of hormonal medications. History of levothyroxine tablets in the last two months.
Dissatisfaction patients to participate in the study.

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B are available to the researcher, Accordingly, 20 blocks were allocated to patients, in each block, 2 were from following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B were treated with Levothyroxine and Placebo tablet, respectively. First, we determine all foursome modes in which half of the individuals are assigned to group A and the other half to group B. Then we assign one of the digits 1 to 6 to each of the foursome combinations (which includes six modes). In the next step, we must randomly select 20 blocks of four and write their combinations in succession. For this we have to make 20 samplings with replacement from a six-member community; 20 times, choose a random number between 1 and 6 and this process will continue until the end of the sampling and the difference between the two groups will not exceed a maximum of two (half the size of the block).

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person will be assigned a study code A and B, which will only be known to the researcher of the type of

groups. The clinical observant and the participants are unaware of the groups. It should be noted that levothyroxine and placebo tablet have been similar in appearance, color, and packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2019-01-13, 1397/10/23

Ethics committee reference number

IR.MEDSAB.REC.1397.092

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

Determine the level of Estrogen

Timepoint

At the beginning of the study (before the intervention) and 2 months after starting the intervention.

Method of measurement

Use of Luminescence quantitative and ELISA methods

2

Description

Determine the level of progesterone

Timepoint

At the beginning of the study (before the intervention) and 2 months after starting the intervention.

Method of measurement

Use of Luminescence quantitative and ELISA methods

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are treated with levothyroxine for two months (50 micrograms daily and fasting 5 days a week) with the aim of Euthyroidism.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group are treated with placebo for two months (fasting 5 days a week).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Farnoosh Attarzadeh

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Vasei Hospital, Asadabady Ave., Sabzevar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Najmeh Rahimi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist and Metabolism

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Latest degree

Subspecialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

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

Sabzevar University of Medical Sciences

Full name of responsible person

Farnoosh Attarzadeh

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work