Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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
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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

Street address

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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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