Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Non-inferiority Randomized Controlled Clinical Trial of the hormonal responses to Levothyroxin made by Aburaihan company and Levothyroxine made by Merck company

Protocol summary

Study aim

The study of clinical responses to Levothyroxine made by Abureihan versus Merck company

Design

This clinical trial includes two groups of hypothyroid patients. The groups are double-blinded, parallel groups, and randomized. Phase 2 consists of 60 patients. Patients are divided into two groups based on cluster randomization

Settings and conduct

Patients will be recalled from a private clinic in Tehran to the Research Institute for Endocrine Sciences. The treatment will be allocated based on the pre-specified double-blinded random allocation while the researchers and patients are blinded to therapy. The drug will be continued for eight weeks. Participants will be evaluated for biochemical assessments, thyroid symptoms, and treatment satisfaction at baseline and end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: New patients with Hypothyroidism: serum TSH level should be 5.06-19.9 mIU/L and serum FT4 less than 0.91 ng/dL. Only new patients who have never taken thyroid treatment Exclusion criteria: Pregnant women People with underlying diseases such as liver failure, renal failure, heart failure People with co-factors that can simulate hypothyroidism symptoms: Low Hgb, Vitamin D and B12 deficiency, and Depression Taking any of the following medications during the trial: Methimazole, PTU, Tamoxifen, drugs containing Estrogen and Progesterone, Corticosteroid, Gastrointestinal medication

Intervention groups

The first group consists of 30 patients with Hypothyroidism who receive Levothyroxine pills made by Merck. The treatment begins with 1.6 micro-gram per kg daily. The second group consists of 30 patients with hypothyroidism who will receive Levothyroxine pills made by the Abureihan company. The treatment begins with 1.6 micro-gram per kg daily.

Main outcome variables

The changes in serum TSH level and serum FT4 level, TSQ and THY-TSQ

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220307054211N1**
Registration date: **2022-05-15, 1401/02/25**
Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**
Update count: **0**

Registration date

2022-05-15, 1401/02/25

Registrant information

Name

Atieh amouzegar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2243 2500

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amouzegar@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-11, 1401/04/20

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Non-inferiority Randomized Controlled Clinical Trial of the hormonal responses to Levothyroxin made by Aburaihan company and Levothyroxine made by Merck company

Public title
Comparison of the hormonal responses to Levothyroxin made by Aburaihan company with Levothyroxine made by Merck company
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New patients with Hypothyroidism: serum TSH level should be 5.06-19.9 mIU/L and serum FT4 less than 0.91 ng/dL. Only new patients who have never taken thyroid treatment.
Exclusion criteria:
Pregnant women People with underlying diseases such as liver failure, renal failure, heart failure People with co-factors that can simulate hypothyroidism symptoms: Low Hgb, Vitamin D and B12 deficiency, and Depression Taking any of the following medications during the trial: Methimazole, PTU, Tamoxifen, Drugs containing Estrogen and Progesterone, Corticosteroid, Gastrointestinal medication
Age
From **20 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two intervention groups based on cluster randomization. Six stratifications will be made based on age and gender. At first, patients will be assigned to three age groups of ≤50y, 51-70y, and >70 y. Under each subgroup, patients will be assigned to male and female. Then under each sex subgroup, patients will be randomly assigned to two treatment groups using the random table. Random sequences will be generated using Random-Allocation software.
Blinding (investigator's opinion)
Double blinded
Blinding description
After performing randomization and special coding, subjects are assigned to groups using concealment, which helps keep physicians, participants, and researchers unaware of the type of treatment being assigned. Standard methods will be used to ensure concealment. Opaque containers will be numbered or coded in order. For single-center clinical trials such as the current trial, we select an expert who does not participate in the trial and can maintain a randomized list. This person is instructed to keep the list private and disclose treatment allocation only after receiving information indicating the patient is eligible and has consented to the trial. Subjects and researchers will be protected from knowing who will be assigned to which treatment (double-blind). Both groups will receive the same pills in appearance, taste, and smell.
Placebo
Not used
Assignment
Parallel
Other design features
The drug will be continued in 2 intervention groups (Levothyroxine made by Merck and Abureihan companies). Patients will be visited 6 and 8 weeks later to measure TSH and FT4 and assess therapy adherence and adverse effects. Drug dosage would be adjusted to maintain serum TSH concentration within 0.5-3 mU/l. Participants will be evaluated at baseline and two consequent follow-ups at six and eight weeks. At the first, second, and last visit at eight weeks, venous blood samples will be collected from all participants to measure serum TSH and FT4. Thyroid symptom questionnaires (TSQ) and thyroid treatment satisfaction questionnaires(ThyTSQ) will be filled out at the first and last visits (TSQ and ThyTSQ).To ensure compliance with drug therapy, the responsible person will check the drug package and count the number of pills intake by direct questioning in 2 weeks intervals by phone call and pill counting at the last visit.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical
Street address
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Yaman St, Tehran Province, Iran
City
Tehran
Province
Tehran
Postal code

1985717413

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.SBMU.ENDOCRINE.REC.1401.008

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

E03.9

ICD-10 code description

Hypothyroidism, unspecified

Primary outcomes

1

Description

Changes of serum TSH level

Timepoint

First day, 6 weeks and 8 weeks after intervention

Method of measurement

Serum TSH and FT4 will be determined on blood samples by the Electrochemiluminescence immunoassay (ECLIA) method, using Roche Diagnostics kits and Roche/Hitachi Cobas e-411 analyzer (GmbH, Mannheim, Germany).

2

Description

Changes of serum FT4 level

Timepoint

First day, 6 weeks and 8 weeks after intervention

Method of measurement

Serum TSH and FT4 will be determined on blood samples by the Electrochemiluminescence immunoassay (ECLIA) method, using Roche Diagnostics kits and Roche/Hitachi Cobas e-411 analyzer (GmbH, Mannheim, Germany).

Secondary outcomes

1

Description

Thyroid symptoms

Timepoint

At the first and last visits

Method of measurement

Thyroid symptom questionnaire (TSQ)

2

Description

Treatment satisfaction

Timepoint

At the first and last visits

Method of measurement

Treatment satisfaction questionnaire (THY-TSQ)

Intervention groups

1

Description

Intervention group number one: This group will receive Levothyroxine pills made by Merck company. They will take 1.6 micro-gram per kg daily before breakfast for eight weeks.

Category

Treatment - Drugs

2

Description

Intervention group number two: This group will receive Levothyroxine pills made by Abureihan company. They will take1.6 micro-gram per kg daily before breakfast for eight weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aburaihan pharmaceutical co.

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
Aburaihan pharmaceutical co.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Atieh Amouzegar
Position
Associate professor
Latest degree
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Person responsible for updating data

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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
These data belong to Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences.
Study Protocol
No - There is not 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

No - There is not 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