

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of The Iron Effect on Thyroid Function in Women with Hypothyroidism

Protocol summary

Study aim

The effect of iron on improving thyroid function in women with hypothyroidism

Design

This study is a double-blind clinical trial. At total, 94 eligible female patients between 20 to 70 years old with hypothyroidism that referred to Amir-al-momenin hospital will enter to the study. patients will be divided into two groups by numbered closed envelopes.

Settings and conduct

All patients will referred to the laboratory of Arak University of Medical Sciences for testing blood samples and the level of T4-TSH-T3. Also iron profiles of patients will measure and record at the time of entry. Then for the first group, levothyroxine with placebo will be prescribed and For the second group, levothyroxine with 100 mg iron per day will be prescribed. Once again after two months, the level of T4-TSH-T3 and iron profiles of patients will measure and record. The results of the patients will be analyze after the end of the treatment. Patients, researcher, physicians and statistical adviser are blind about the type of drug and groupings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 94 female patients between 20 to 70 years old with hypothyroidism will be entering to the study. Exclusion criteria: the event of pregnancy, breastfeeding or chronic diseases that occurs during the study, they will be excluding from the study.

Intervention groups

For the first group, levothyroxine with placebo will be prescribed and For the second group, levothyroxine with 100 mg iron per day will be prescribed.

Main outcome variables

T3, T4, TSH, serum iron, ferritin and hemoglobin levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151114025031N7**

Registration date: **2018-02-24, 1396/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-24, 1396/12/05**

Update count: **0**

Registration date

2018-02-24, 1396/12/05

Registrant information

Name

Fatemeh Rafiei

Name of organization / entity

Arak University of Medical Science

Country

Iran (Islamic Republic of)

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+98 86 3226 5732

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-29, 1396/08/07

Expected recruitment end date

2018-03-27, 1397/01/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Iron Effect on Thyroid Function in Women with Hypothyroidism

Public title

Evaluation of The Iron Effect on Thyroid Function in Women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hypothyroidism with TSH in the range of 0.05 to 5 mu/l, which with the use of levothyroxine for at least 6 months or more remains in this range. Female Between 20 to 70 years old

Exclusion criteria:

Pregnancy that occurs during the study Breastfeeding that occurs during the study Chronic diseases, such as liver and kidney disease, that occurs during the study Gi intolerance to iron tablets Patients with thyroid cancer

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

For Blindness and randomization will be used from numbered closed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, researcher, physicians and statistical adviser do not know about the type of drug and groupings.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committe of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IRARAKMU.REC.1396.154

Health conditions studied**1****Description of health condition studied**

Other hypothyroidism

ICD-10 code

E03

ICD-10 code description

Other hypothyroidism

Primary outcomes**1****Description**

T3 Level

Timepoint

Before and two months after intervention

Method of measurement

enzyme-linked fluorescence assay (ELFA)

2**Description**

T4 Level

Timepoint

Before and two months after intervention

Method of measurement

enzyme-linked fluorescence assay (ELFA)

3**Description**

TSH Level

Timepoint

Before and two months after intervention

Method of measurement

enzyme-linked fluorescence assay (ELFA)

4**Description**

Ferritin Level

Timepoint

Before and two months after intervention

Method of measurement

enzyme-linked fluorescence assay (ELFA)

5

Description

Hemoglobin Level

Timepoint

Before and two months after intervention

Method of measurement

enzyme-linked fluorescence assay (ELFA)

6

Description

Serum Iron Level

Timepoint

Before and two months after intervention

Method of measurement

enzyme-linked fluorescence assay (ELFA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Levothyroxine with 100 mg iron per day for 2 months

Category

Treatment - Drugs

2

Description

Control group: Levothyroxine with 100 mg placebo per day for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al-Momenin Hospital of Arak

Full name of responsible person

Dr. Zahra Shiravand

Street address

Amir-al-Momenin Hospital, Basij Square

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3848176941

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it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Arjmandzadegan

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Zahra Shiravand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

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

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

Data Dictionary

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