Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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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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
Street address
Arak University of Medical Sciences, Basij Square, Sardasht
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info@arakmu.ac.ir
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
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Internal Medicine
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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