# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

14 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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+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
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3417 3601
**Email**
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
**Other areas of specialty/work**
Internal Medicine
**Street address**
Amir-al-Momenin Hospital, Basij Square
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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