Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of ferrous sulfate on thyroid function in pregnant women with acquired hypothyroidism in the second trimester of pregnancy

Protocol summary

Study aim
Determining whether correcting iron deficiency in pregnancy helps to improve thyroid function

Design
Clinical trial with control group, with parallel groups, single blind, randomized, phase 3 on 48 patients, all information will be done using spss version 21.

Settings and conduct
This study will be conducted as a randomized clinical trial study on pregnant women with acquired hypothyroidism referred in the second trimester of pregnancy. This study is a blind strain and the participants are blind and uninformed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: pregnant mothers with a positive pregnancy test result, age 20 to 35 years, and the pregnancy time is the second trimester of pregnancy, and informed consent will be obtained from all patients. Exclusion criteria were: suffering from chronic diseases (such as diabetes). Gastrointestinal intolerance of iron pills, all cancers and neoplasms, especially thyroid cancer.

Intervention groups
.The study will be one-way blind in two groups, group A is the control group and group B is the intervention group. At the beginning of the study, 5 cc of blood will be taken from each patient, then for the intervention group, ferrous sulfate tablets, each tablet containing 50 mg of elemental iron, will be given two tablets equivalent to 100 mg of elemental iron daily, and for the control group, placebo tablets will be given daily. Two numbers will be given. After three months, 5 cc of blood will be collected from each group and the tests will be repeated in the same laboratory with the same kits.

Main outcome variables
Ferritin - TSH _hemoglobin _T3_T4 _ TIBC

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240211060962N1**
Registration date: **2024-06-01, 1403/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-01, 1403/03/12**
Update count: **0**

Registration date
2024-06-01, 1403/03/12

Registrant information

Name
Mobina pourghahramani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3346 8815

Email address
poourmobinaaa97@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of ferrous sulfate on thyroid function in pregnant women with acquired hypothyroidism in the second trimester of pregnancy

Public title
Investigating the effect of ferrous sulfate on thyroid function in pregnant women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 20 to 35 years Second trimester pregnancy is considered Primary acquired thyroid disease Obtaining informed consent and explanation to patients The bmi of pregnant mothers is considered within the normal range (18.5-24.5)

Exclusion criteria:
Having diabetes and high blood pressure Suffering from chronic diseases, including chronic kidney failure and liver failure Getting cancer and neoplasm, especially thyroid cancer Dissatisfaction of patients

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, we use a table of random numbers. Suppose we are conducting a study in which there are two groups A and B. We assign each odd number to group A and each even number to group B. We close our eyes and Place your finger in the table of random numbers and write down the number of its column and row and specify the direction of your movement in this table. Suppose our starting point is the number 5 at the intersection of column 07 and row 07 and the direction of our movement is horizontal. to the right, so the first patient with the number 5 receives treatment A and we continue in the same way until the end. The allocation of the next patient is not predictable and this allocation is not one in between.

Blinding (investigator's opinion)
Single blinded

Blinding description
One way of blinding is the use of a placebo, that is, an inert substance that has the same taste and smell as Taher, although the use of a placebo in itself does not guarantee that the patients were blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences (Research Ethics Committee)

Street address
Hasani Street, Kosar Hospital

City
Urmia

Province
West Azarbaijan

Postal code
5167869456

Approval date
2024-01-29, 1402/11/09

Ethics committee reference number
IR.UMSU.REC.1402.324

Health conditions studied

1

Description of health condition studied
Primary acquired hypothyroidism

ICD-10 code
E01.8

ICD-10 code description
Other iodine-deficiency related thyroid disorders and allied conditions

Primary outcomes

1

Description
Primary outcome variable: pregnant women with primary acquired hypothyroidism or those whose tsh is greater than 4.5 mIU/L

Timepoint
Measurement of thyroid hormones at the beginning of the intervention (before the start) and 2 months after the start of ferrous sulfate

Method of measurement
The method of measurement is through laboratory tests, 5 cc of blood will be taken from each patient, and for the test, vidas kits for thyroid hormones will be taken.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At the beginning of the study, 5 cc of blood will be collected from each patient and for testing, it will be done using vidas kits for ferritin and thyroid hormones (one from each kit) and Ferozin method to check serum transferrin and iron (one kit from each).) and it will be done in a laboratory (Kawsar Women's Comprehensive Laboratory in Urmia). Then, for the intervention group, ferrous sulfate tablets from Rosdaro Pharmaceutical Factory, each tablet containing 50 mg of elemental iron, will be given two tablets equivalent to 100 mg of elemental iron per day. After three months, 5 cc of blood will be collected from each group and the tests will be repeated in the same laboratory with the same kits.

Category
Treatment - Drugs

2

Description
Control group: At the beginning of the study, 5 cc of blood will be collected from each patient and for testing, it will be done using vidas kits for ferritin and thyroid hormones (one from each kit) and Ferozin method to check serum transferrin and iron (one kit from each).) and it will be done in a laboratory (Kawsar Women's Comprehensive Laboratory in Urmia). And for the control group, two placebo pills will be given daily. After three months, 5 cc of blood will be collected from each group and the tests will be repeated in the same laboratory with the same kits.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Women's Hospital in Urmia
Full name of responsible person
Mobina Pourghahramani
Street address
Hasani Street Kosar Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Leila Chodari
Street address
Hasani Street Kosar Hospital
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
My financial source is a student, and because I am a campus student, no fees are charged by the university.
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Mobina Pourghahramani
Position
Doctoral student of general medicine
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
In this study, only a part of the data, such as the information related to the main outcome or the like, can be shared after making people unidentifiable.

When the data will become available and for how long
The access period starts 3 months after the thesis defense

To whom data/document is available
The data of this study will be available only to researchers working in medical and scientific academic institutions

Under which criteria data/document could be used
Ethical considerations should be observed in all relevant aspects and analyses

From where data/document is obtainable
Send a message to email poormobinaa97@gmail

What processes are involved for a request to access data/document
Examining the person requesting information and the reason for his request for information, observing ethical considerations and checking in the university council, and sending the information if necessary.

Comments