

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of iron and vitamin C co-supplementation on thyroid hormones, hematological parameters, oxidative stress, inflammation, and quality of life in hyperthyroidism patients

Protocol summary

Study aim

Determining the effect of combined iron and vitamin C supplementation on thyroid hormone status, blood parameters, and quality of life in patients with hyperthyroidism

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients

Settings and conduct

In this study, people with hyperthyroidism, referred to Firoozgar Hospital, who were eligible to participate in the study based on inclusion and exclusion criteria, are asked to complete a written informed consent form. Individuals will be randomly assigned to one of two groups receiving the intervention and a placebo. Then, at the beginning and end of the study, 10 cc of blood will be taken from people and the levels of inflammatory factors, thyroid hormones and blood factors will be measured. Double blind study (Participants and researcher). Iron vitamin c and placebo tablets will be placed into identical containers and all investigators and participants will be blinded to the random assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women over 18 years of age with hyperthyroidism with body mass index 18.5 to 30 kg / m², hemoglobin level less than 12.7 and 13 g / dL in men and women, start drug treatment Exclusion criteria: autoimmune diseases, chronic, infectious and other thyroid disorders, taking vitamin C iron supplement in the last month

Intervention groups

Intervention group: 40 men and women with hyperthyroidism receive two tablets of 27 mg of iron and 100 mg of vitamin C daily for 8 weeks each. Placebo group: 40 men and women with hyperthyroidism take two placebo tablets (containing maltodextrin) daily, which are similar in appearance to iron and vitamin C

supplements, for 8 weeks each.

Main outcome variables

The primary Outcome in this study is TSH level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N27**

Registration date: **2022-03-04, 1400/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-04, 1400/12/13**

Update count: **0**

Registration date

2022-03-04, 1400/12/13

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4734

Email address

vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of iron and vitamin C co-supplementation on thyroid hormones, hematological parameters, oxidative stress, inflammation, and quality of life in hyperthyroidism patients

Public title
Effect of iron and vitamin C co-supplementation in hyperthyroidism patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Men and women over 18 years of age with newly diagnosed hyperthyroidism Body mass index 18.5-30 kg / m² Hemoglobin level less than 12.7 g / dl for women and less than 13 g / dl for men Start a medication program No autoimmune diseases and chronic diseases such as diabetes, hypertension, kidney, liver, gallbladder, thyroid, parathyroid, bone, gastrointestinal and hyperphosphatemia disorders No infectious diseases, malignancies and severe bleeding in the last 2 months No thalassemia and other blood disorders Do not use hormonal drugs, anticonvulsants, cholesterol and fat lowering drugs, antacids, blood thinners, and laxatives. Do not take iron and vitamin C supplements during the last month No history of other thyroid disorders In the case of women, the absence of abnormal and irregular menstrual cycles No pregnancy and lactation Willingness to cooperate
Exclusion criteria:
 Having any acute illness Changes in medications Non-regular use of supplements and acceptance rate less than 90% Migration Exclusion based on personal preference of participants

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomized allocation performing, permuted block randomization will be used by blocks with size of 4. According to the sample size of 80 subjects, 20 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes

will be used on the drug boxes that is generated by the software. Participants will be entered into study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to performing the double-blinded of study, before study beginning, the canisters containing tablets can be provided by someone other than the researcher, and the placebo tablets in appearance are similar to the supplementation tablets and the researcher are not be aware about the allocation of studied subjects in each group during the evaluation of the studied outcomes until the end of the intervention period.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Hemmat Express way, Iran University of Medical Science

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.IUMS.FMD.REC.1400.601

Health conditions studied

1

Description of health condition studied

Hyperthyroidism

ICD-10 code

E05

ICD-10 code description

Thyrotoxicosis [hyperthyroidism]

2

Description of health condition studied

Iron deficiency anemia

ICD-10 code

D50

ICD-10 code description

Iron deficiency anemia

Primary outcomes

1

Description

thyroid stimulating hormone

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

The level of TSH in serum is with ELISA method

Secondary outcomes

1

Description

High-sensitive C-reactive protein (hs-CRP)

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

The level of Hs-CRP in serum is with ELISA method

2

Description

Free thyroxine hormone levels

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

The level of FT4 in serum with ELISA method

3

Description

free triiodothyronine Hormone Levels

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

The level of FT3 in serum with ELISA method

4

Description

Malondialdehyde

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

The level of MDA in serum with ELISA method

5

Description

Total antioxidant capacity

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

The level of TAC in serum with ELISA method

6

Description

Hemoglobin

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

Using an automated Hematology analyzer

7

Description

Red blood cell

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

Using an automated Hematology analyzer

8

Description

mean corpuscular volume

Timepoint

At the baseline and after 8 weeks of intervention

Method of measurement

Using an automated Hematology analyzer

Intervention groups

1

Description

Intervention group: 40 men and women with hyperthyroidism receive two tablets of 27 mg of iron supplement and 100 mg of vitamin C daily for 8 weeks each.

Category

Treatment - Other

2

Description

Control group: 40 men and women with hyperthyroidism, each receiving 8 placebo tablets (containing maltodextrin) daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Fatemeh golgiri

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Tehran, Valiasr Square, Karim Khan Zand St., Beh Afarin St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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)**

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

A part of the data will be shared, such as primary outcomes

When the data will become available and for how long

Four months after the publication of the results

To whom data/document is available

Researchers and students of university

Under which criteria data/document could be used

Four months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Department of nutrition, school of health, Iran university of medical sciences, Hemmat highway, Tehran. Phone number: 0098 21 86704743. E-mail: vafa.m@iums.ac.ir

What processes are involved for a request to access data/document

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Department of nutrition, school of health, Iran university of medical sciences, Hemmat highway, Tehran. Phone number: 0098 21 86704743. E-mail: vafa.m@iums.ac.ir

Comments