

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effects of omega-3 supplementation compared to placebo on anthropometric measurements, thyroid hormone and anti-tpo concentrations, and systemic inflammation in patients with Hashimoto's disease.

Protocol summary

Study aim

Investigating the effects of taking omega-3 supplements on the concentration of thyroid hormones T4 and T3 and Anti-tpo and systemic inflammation (hs-crp) in patients with Hashimoto's disease

Design

A phase 2 controlled, parallel-group, triple-blinded, randomized clinical trial on 60 patients. Randomization will be done using randomized blocks of size 4.

Settings and conduct

The Clinic of Nutrition Faculty of Shahid Beheshti University of Medical Sciences in Tehran is the host of this study on Hashimoto's thyroiditis patients. People will be divided into two groups of supplement and placebo and will receive supplement/placebo for 3 months. This study will be triple-blind and the participants will not be aware of the supplement or placebo they will be receiving. Two people will prepare the omega-3 supplement packets and the placebos, and steps will be taken to ensure participant confidentiality.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to cooperate; suffering from Hashimoto's disease (endocrine specialist diagnosis); age of 20-70 years; Body mass index between 25-35. Exclusion criteria: pregnancy and breastfeeding; kidney Diseases; Following non-routine weight loss diets up to three months before the start of the study; taking anticoagulant, slimming and fat burning drugs, fiber powder; mineral, vegetable and fiber vitamin supplements; Presence of any blood clotting problems

Intervention groups

Intervention group: Two 1000-mg omega-3 capsules per day with breakfast and dinner. Control group: Omega-3 placebo group: two 1000mg Omega-3 placebo (microcrystalline cellulose) capsules with breakfast and

dinner.

Main outcome variables

Waist circumference; hips circumference; waist to hip ratio; body mass index; Triiodothyronine(T3); Thyroxine(T4);Thyroid Stimulating Hormone (TSH); Anti-thyroid peroxidase(Anti-TPO);High sensitivity C-reactive protein (hs-Crp)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150815023617N7**

Registration date: **2023-11-18, 1402/08/27**

Registration timing: **prospective**

Last update: **2023-11-18, 1402/08/27**

Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 22077424

Email address

golbonsohrab@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effects of omega-3 supplementation compared to placebo on anthropometric measurements, thyroid hormone and anti-tpo concentrations, and systemic inflammation in patients with Hashimoto's disease.

Public title

The effects of omega-3 supplementation in patients with Hashimoto's disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate diagnosed with Hashimoto's thyroiditis (by endocrinologist) aged between 20-70 Body mass index between 25 - 35

Exclusion criteria:

Pregnancy or lactation Kidney disorders Following weight loss diets 3 months before the beginning of study Use of anti-coagulant agents, slimming and fat-burning drugs, fiber powder Presence of any blood clotting issues

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly divide people into two groups, first the patients are classified according to gender and the omega-3 group is marked with A and the placebo group is marked with B. Then, 13 blocks will be randomly selected from the table of blocks of size 4 that are combinations between A and B, and these blocks will be placed one after the other. Then 50 envelopes are prepared and the name of group A or B is placed in each envelope, so that the order of the envelopes is the same as the order of letters A and B in the selected blocks. Then the envelopes are opened in order and people are assigned to groups A and B. Omega 3 group people will receive 1000 mg of Omega 3 daily for 3 months and group B will receive a placebo that is completely similar

in taste, color and appearance to Omega 3 supplements and contains sunflower oil.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to perform this research in a three blinded method, at the beginning of the study, the capsules containing omega-3 supplements or placebo are coded by the factory as A and B so that the lack of information of the researcher, statistical analyst and patients of the type of supplements received by each group is observed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University Medical Sciences.

Street address

Sixth floor, building number two, Shahid Beheshti University of Medical Sciences, Arabi Street, Yemen Street, Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

19395-4631

Approval date

2023-08-14, 1402/05/23

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1402.036

Health conditions studied

1

Description of health condition studied

Hashimoto's disease

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

High sensitivity C-reactive protein (hs-CRP)

Timepoint

at the beginning and end of the study

Method of measurement

ELISA method

2**Description**

Anti-thyroid peroxidase (Anti-TPO)

Timepoint

at the beginning and end of the study

Method of measurement

ELISA method

3**Description**

Thyroxine (T4)

Timepoint

at the beginning and end of the study

Method of measurement

ELISA method

4**Description**

Triiodothyronine (T3)

Timepoint

at the beginning and end of the study

Method of measurement

ELISA method

5**Description**

Thyroid Stimulating Hormone (TSH)

Timepoint

at the beginning and end of the study

Method of measurement

ELISA method

6**Description**

Waist circumference

Timepoint

at the beginning and end of the study

Method of measurement

measuring tape

7**Description**

hips circumference

Timepoint

at the beginning and end of the study

Method of measurement

measuring tape

8**Description**

Waist to hips ratio

Timepoint

at the beginning and end of the study

Method of measurement

calculation

9**Description**

Body Mass Index (BMI)

Timepoint

at the beginning and end of the study

Method of measurement

Calculation based on the weight and height of the patient

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The group receiving omega-3 supplements should take two capsules of 1000 mg of omega-3 per day with the main meals of breakfast and dinner.

Category

Treatment - Other

2**Description**

Control group: receiving omega-3 placebo including two 1000mg capsules of omega-3 placebo (microcrystalline cellulose) daily with breakfast and dinner

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taban polyclinic of endocrine disorders

Full name of responsible person

Golbon Sohrab

Street address

No 100, End of Derakhti st, Dadman Blvd, Gharb town, Tehran

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Phone

+98 21 2237 7250

Email

Info@tabanclinic.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Morteza Abdolahi

Street address

No. 7, Shahid Hafezi St. (West Arghavan), Shahid Farahzadi Blvd, Qods Town.

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Email

golbonsohrab@sbmu.ac.ir

Web page address

<https://nutrition.sbmu.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town

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Position

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Person responsible for updating data

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Position

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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

Only part of the data is shared, such as the primary outcome.

When the data will become available and for how long

The start of the access period is 12 months after printing the results.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The documentation can only be used for more complete studies in this field.

From where data/document is obtainable

Dr Golbon Sohrab Faculty member (assistant professor) at Faculty of Nutrition Sciences & Food Technology, Shaheed Beheshti University of Medical Sciences Email: golbonsohrab@sbmu.ac.ir

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

The communication will be possible through the electronic mail given in the previous section.

Comments