

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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@sbm.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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1981616931

##### **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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2208 6349

**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

**Street address**

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

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**Email**

golbonsohrab@sbmu.ac.ir

## Person responsible for scientific 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.

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## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Golbon Sohrab

**Position**

Assistant professor

**Latest degree**

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**Phone**

+98 21 2207 7425

**Email**

golbonsohrab@sbmu.ac.ir

## 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**