

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Aug 2026

Evaluation of the effect of omega 3 fatty acid (fish oil) on serum levels of inflammatory factors in patients with hashimoto thyroiditis

Protocol summary

Summary

Objectives: This study conducted to evaluate the effect of omega 3 fatty acid (fish oil) on serum levels of inflammatory factors such as TNF- α , hs_CRP and ESR in patients with hashimoto thyroiditis. **Design:** A randomized, double-blind, placebo-controlled clinical trial was conducted on 60 hashimoto patients who referred to Urmia Emam KHomeini Hospital. **Setting and conduct:** Patients were divided randomly into 2 groups; intervention group received 3 grams per day omega-3 supplement and placebo group tablets containing 3 grams edible paraffin 3 times in a day for 8 weeks. **Participants:** inclusion criteria were Hashimoto patients over 18 years. Exclusion criteria including: patients with rheumatoid arthritis; celiac disease; pernicious anemia; systematic lupus erythematosus and other autoimmune disease and other acute or chronic infections disease; postmenopausal women; pregnant and Lactating women; taking drugs such as warfarin; aspirin; gamma interferon; smoking; using contraceptive drugs; Seasonal allergies; allergy to the fish or oil fish; eating fish over twice in week. TNF- α , hs_CRP and ESR before and after 8 weeks intervention were compared between two groups. The 24-hour dietary recall questionnaire was filled for participants in before and after the intervention duration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050629508N6**

Registration date: **2017-07-06, 1396/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-06, 1396/04/15

Registrant information

Name

Rasoul Zarrin

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9935

Email address

rasoul.zarrin@uqconnect.edu.au

Recruitment status

Recruitment complete

Funding source

by my own

Expected recruitment start date

2016-09-24, 1395/07/03

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of omega 3 fatty acid (fish oil) on serum levels of inflammatory factors in patients with hashimoto thyroiditis

Public title

Evaluation of the effect of omega 3 fatty acid in patients with hashimoto thyroiditis

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Hashimoto patients over 18 years.

Exclusion criteria: patients with rheumatoid arthritis; celiac disease; pernicious anemia; Systematic lupus

erythematous and other autoimmune disease and other acute or chronic infections disease; postmenopausal women; pregnant and lactating women; taking drugs such as warfarin; aspirin; gamma interferon; smoking; using contraceptive drugs; Seasonal allergies; allergy to the fish or oil fish; eating fish over twice in week.

Age

From **17 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This study was conducted as double-blind. The researcher and participants were unaware that patients randomized in which groups (the intervention or placebo).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat Ave, Urmia, Iran

City

Urmia

Postal code

Approval date

2016-11-16, 1395/08/26

Ethics committee reference number

IR.UMSU.REC.1395.306

Health conditions studied

1

Description of health condition studied

hashimoto disease

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

TNF- α (tumor necrosis factor alpha)

Timepoint

before and 8 week after intervention

Method of measurement

laboratory kit

2

Description

ESR (erythrocyte sedimentation rate)

Timepoint

before and 8 week after intervention

Method of measurement

laboratory kit

3

Description

hs_CRP (high-sensitivity C-reactive protein)

Timepoint

before and 8 week after intervention

Method of measurement

laboratory kit

Secondary outcomes

1

Description

24 hour recall

Timepoint

before and 8 week after intervention

Method of measurement

24 hour recall questionnaire

Intervention groups

1

Description

Intervention group: received omega-3 supplement for 8 weeks 3 grams per day in three divided doses (one pill three times a day after meals) containing 180mg eicosapentaenoic acid and 120mg docosahexaenoic acid

Category

Other

2

Description

Placebo group: took placebo pills containing edible paraffin 3 times in a day for 8 weeks

Category

Placebo

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

Urmia Emam Khomeini Teaching Hospital

Full name of responsible person

Dr. Rasoul Zarrin

Street address

Emam Khomeini Hospital, Modarres Ave, Ershad Street, Urmia, Iran

City

Urmia

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

by my own

Full name of responsible person

Ms Mahsa Ghamari

Street address

Emam Khomeini Hospital; Ershad Street; Modarres Ave; Urmia

City

Urmia

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

by my own

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Urmia University of Medical Science

Full name of responsible person

Dr. Rasoul Zarrin

Position

Assistant profesor of Nutrition

Other areas of specialty/work**Street address**

Department of Nutrition, School of Medicine, Nazlou Pardis, Sero Road, Urmia

City

Urmia

Postal code

81351-57157

Phone

+98 44 3346 9935

Fax

+98 44 3345 7277

EmailRasoul.zarrin@uqconnect.edu.au,
wwzarrin@yahoo.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Urmia University of Medical Science

Full name of responsible person

Dr. Rasoul Zarrin

Position

Assistant Profesor of Nutrition

Other areas of specialty/work**Street address**

Department of Nutrition, School of Medicine, Nazlou Pardis, Sero Road, Urmia

City

Urmia

Postal code

81351-57157

Phone

+98 44 3346 9935

Fax

+98 44 3345 7277

Email

Rasoul.zarrin@uqconnect.edu.au

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Urmia University of Medical Science

Full name of responsible person

Ms Mahsa Ghamari

Position

MSc of Nutrition

Other areas of specialty/work**Street address**

Emam Khomeini Hospital; Ershad Street; Modarres Ave; Urmia

City

Urmia

Postal code

81351-57157

Phone

+98 44 3346 9935

Fax**Email**

gh.mahsa89@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty