

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of Omega3 Function in the Treatment of Chronic Urticarial, with Clinical Evaluation and Adaptive Innate Immune Response in the double-blind Model

Protocol summary

Study aim

Since there is Still no Standard Treatment for the Treatment of Chronic Urticaria, and most of the Chemical Drugs used in this Area are Complicated, the Use of Edible Compounds that have Anti-Inflammatory Effects and May Play a Role in the Improvement of the Symptoms of the Disease. This Study is Intended to Evaluate the Therapeutic Effects of Omega-3 in Patients With Chronic Urticaria. This Randomized, double-blind, Placebo-Controlled Study was Conducted on 60 Patient

Design

In this Study, 60 Patients with Chronic Urticaria who are Eligible to Enter the Study are Selected. Participants are Randomly Divided into Intervention and Control Groups and each Participant is Assigned a code. The Sample Size is 10cc and the Intervention is Omega3, and the Intervention time will be taken after the Sample is taken from the Patient.

Settings and conduct

After Sampling, a Molecular Study will be Done at the Mazandaran Medical Research Center and a Clinical Evaluation will be Carried out by a Specialist at the Bu-Ali Hospital. In this Study, a Researcher who Evaluates the Clinical and Delivery Conditions of the Drug is not Aware of how the Drug is Administered and the Medications are Delivered to the Patient in Packaged by the Pharmacy and the Pharmaceutical Number will be Recorded in the list of Patients' Names

Participants/Inclusion and exclusion criteria

Criteria for entry: Chronic Idiopathic Urticaria - Age between 10 and 40 Years - Receiving Antihistamines Exit Eriteria: Concomitant illness, whether Allergic or non-Allergic - Use of non-Antihistamine Medication -Age less than 10 and above 40

Intervention groups

In this study, Omega3 was Used as an Intervention and its Effects on Chronic Urticaria have been Studied. The

Control Group in this Study is Chronic Urticaria who will Receive Placebo Omega3 Instead of Omega3

Main outcome variables

The main Consequences of this Study were the Reduction of Clinical Symptoms, such as Reduce Itching caused by Hives, Reduce Urticaria waste and Decreased Antihistaminic use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110531006660N5**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Javad Ghafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 0054

Email address

ghafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Omega3 Function in the Treatment of Chronic Urticarial, with Clinical Evaluation and Adaptive Innate Immune Response in the double-blind Model

Public title

Effect of Omega3 in Treatment of Chronic Urticaria

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic Idiopathic Urticaria Age between 10 and 40 Years Old Receiving Antihistamines Patient Approval Completion of Treatment for at least 30 Days

Exclusion criteria:

Concomitant illness; whether allergic or non-allergic ; Use of non-Antihistamine Medication Age Less than 10 and above 40 Acute Hives Physical Urticaria Hypersensitivity or Antihistamine Anaphylaxis Pregnant Women

Age

From **10 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this Study, Simple Randomization Method is Used with the Numerical Table

Blinding (investigator's opinion)

Double blinded

Blinding description

In this Study, Research Fellow, Specialist Evaluating the Clinical Conditions and the Delivery of the Drug is not Aware of how the Drug is Administered, and the Drugs will be Delivered to the Patient in the Numbered Package to the Patient and the Packet Number will be Recorded in the list of Patients. As well as those who Receive the drug, are not Aware of the Placebo, and are being Evaluated

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

Street address

Sari, Khazar Square, Farah Abad Road, Km 18, Complex of the Great Prophet

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2017-07-31, 1396/05/09

Ethics committee reference number

3051

Health conditions studied**1****Description of health condition studied**

Chronic urticaria

ICD-10 code

L50.1

ICD-10 code description

Idiopathic urticaria

Primary outcomes**1****Description**

clinical resolution of urticaria

Timepoint

before and after treatment

Method of measurement

UAS7

2**Description**

Thymic Stromal Lymphopoietin (TSLP)

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Reverse Transcription Polymerase Chain Reaction (RT-PCR) and Enzyme-Linked Immunosorbent Assay (ELISA)

3

Description

Interferon Gama

Timepoint

Before intervention and 3 months after intervention

Method of measurement

RT-PCR , ELIZA

4

Description

Interleukine4 (IL4)

Timepoint

Before intervention and 3 months after intervention

Method of measurement

RT-PCR , ELIZA

5

Description

IL35

Timepoint

Before intervention and 3 months after intervention

Method of measurement

RT-PCR , ELIZA

6

Description

IL32

Timepoint

Before intervention and 3 months after intervention

Method of measurement

RT-PCR , ELIZA

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Omega3 Containing 180 mg of EPA and 120 mg of DHA, one Daily for 3 Months.

Category

Treatment - Drugs

2

Description

Intervention group: This Group will Receive the Placebo- Omega-3 drug

Category

Placebo

3

Description

Control group: Omega-3 Placebo, one Daily for 3 Months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Boalisina Hospital

Full name of responsible person

Javad Ghaffari

Street address

Bu Ali Sina Hospital, Pasdaran Blvd

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+98 11 3334 3018

Email

Ghaffari@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Complex of the Great Prophet, Km 18, Farah Abad Road, Khazar Square, Sari, Mazandaran

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Javad Ghaffari

Position

Asthma and allergy specialist

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

Street address

Research and Technology Dept, Building No. 2,
Teacher's Square, Teacher's Street

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Fax**Email**

ghafari@mazums.ac.ir

Web page address**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Javad Rajabi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Immunology

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Plaque 33, Baharestan 6, Resalat neighborhood,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Javad Ghaffari. Dr Alireza Rafiei

Position

Asthma and allergy specialist- PhD of immunology

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

Street address

Research and Technology Dept, Building No. 2,
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City

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Province

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Postal code

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Fax**Email**

ghafari@mazums.ac.ir

Web page address

Person responsible for updating data

Contact

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, all the Information on the main Outcome that Includes the Patient's clinical Recovery, as well as the Side Effects Including the Evaluation of serum proteins, Including cytokines, are Shared after taking the Drug

When the data will become available and for how long

The time to Start Accessing Data will be one Month after the Data is Printed

To whom data/document is available

The Data in this Study is Available to Researchers in Academic and Scientific Institutions as well as in Non-Related Fields.

Under which criteria data/document could be used

The Data is Available after Printing and the Specified time Period and is used to Improve the Scientific Level

From where data/document is obtainable

Dr.Javad Ghaffari Email: Ghafari@mazumse.ac.ir Contact Number: 09113510359

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

This Data will be Available to the Applicant one Month

after Printing
Comments