Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 11 3326 0054

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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 (ELIZA)

3

Description
Interferon Gama
Timepoint
Before intervention and 3 months after intervention
Method of measurement
RT-PCR و ELIZA

4

Description
Interleukine4 (IL4)
Timepoint
Before intervention and 3 months after intervention
Method of measurement
RT-PCR و ELIZA

5

Description
IL35
Timepoint
Before intervention and 3 months after intervention
Method of measurement
RT-PCR و ELIZA

6

Description
IL32
Timepoint
Before intervention and 3 months after intervention
Method of measurement
RT-PCR و 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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48157-33971
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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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Ghafari@mazums.ac.ir
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
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Research and Technology Dept, Building No. 2, Teacher's Square, Teacher's Street
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Person responsible for scientific inquiries

Contact

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Dr.Javad Ghaffari. Dr Alireza Rafiei
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Asthma and allergy specialist- PhD of immunology
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Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Javad Rajabi
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Bachelor
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Immunology
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Fax
Email
javadrajabi26@gmail.com
Web page address

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