

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluation of anti-inflammatory effects of omega-3 in children with asthma based on clinical symptoms, spirometry and inflammatory and anti inflammatory cytokines in serum

Protocol summary

Summary

Asthma is a disease of conducting airways and there is a general agreement that airway inflammation is likely critical components of asthma pathogenesis. Omega-3 fatty acids competitively inhibit the formation of prostaglandins and leukotrienes derived from arachidonic acid. This study was design to identify the effect of omega-3- fatty acids on respiratory symptoms, airway function and numerous cytokines including IFN- γ , IL-1 β , IL-2, IL-4, IL-5, IL- 6, IL-9, IL-10, IL-12, IL-13, IL-17A, IL-22 and TNF- α in patients with persistent asthma. Fifty families who has a child with proven persistent asthma registered to this study. After obtaining informed consent from the patients' parents, demographics characteristics were collected. The patients were scheduled to take 1000 mg omega-3 fish oil (Best Formulations Inc., LA, CA, USA) in the form of soft gel capsules daily for consecutive three months. Patients with a history of allergy to seafood, those under treatment with anti-interleukin and those develop side effects such as nausea and vomiting were excluded. At the beginning of the study and the end of three months after intervention phase, the patients were assessed for subjective symptoms; pulmonary function test and measuring cytokines. Each child is serving as their own control for results. Recruitment start date will be during winter 2014.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111419940N1**

Registration date: **2014-12-09, 1393/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-09, 1393/09/18

Registrant information

Name

Mozhgan Moghtaderi

Name of organization / entity

Allergy Research Center- Shiraz University of Medical Sciences, Shiraz, Iran

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 2587

Email address

moghtadery@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research of Shiraz University of Medical Sciences

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of anti-inflammatory effects of omega-3 in children with asthma based on clinical symptoms, spirometry and inflammatory and anti inflammatory cytokines in serum

Public title

The effects of omega-3 in children with asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children with asthma diagnosed by sub specialist of asthma and allergy Exclusion criteria: history of allergy to seafood; those under treatment with anti- leukotrienes and aspirin; side effects such as nausea and vomiting

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Shiraz University Ethics Committee

Street address

Zand street

City

Shiraz

Postal code**Approval date**

2012-02-23, 1390/12/04

Ethics committee reference number

CT-90-3823;CT-90-3812; CT-90-3829

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

Asthma

ICD-10 code

J45.0

ICD-10 code description

Predominantly allergic asthma

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

Respiratory symptoms including cough and wheeze

Timepoint

pre intervention and 3 months after intervention

Method of measurement

Questionnaire based on cough and wheeze in day and night

Secondary outcomes**1****Description**

pulmonary function

Timepoint

before intervention and after 3 months intervention

Method of measurement

spirometry

2**Description**

inflammatory and anti inflammatory cytokines

Timepoint

pre intervention and 3 months after intervention

Method of measurement

using flowcytometry

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

1000 mg Omega-3fish oil (Best Formulations Inc., LA, CA, USA) in the form of softgel capsules including 180 mg EPA (icosapentaenoic acid) and 120 mg DHA (docosahexaenoic acid) daily for consecutive three months.

Category

Treatment - Drugs

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

Aliasghar Hospital, Shiraz University of Medical Sciences

Full name of responsible person

Shirin Farjadian

Street address**City**

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research, Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

7th floor, Zand street , Vice-Chancellery of Research

City

Shiraz

Grant name

3823-3812-3829

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

Yes

Title of funding source

Vice-Chancellery of Research, Shiraz University of Medical Sciences

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**

Allergy Research Center, Shiraz University of Medical Sciences

Full name of responsible person

Mozhgan Moghtaderi

Position

Board of subspecialty clinical immunology and allergy

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

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Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Department of immunology, Shiraz University of Medical Sciences

Full name of responsible person

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**Email****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