Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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-1β, 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)

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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
Questionnarie 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 subspeciality clinical immunology and allergy
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Person responsible for scientific inquiries

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Person responsible for updating data

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mozhgan Moghtaderi
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00
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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