Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of eicosapentaenoic acid in the treatment of pediatric atopic dermatitis a randomized double-blind controlled trial

Protocol summary

Study aim
Evaluating the effect of dietary supplementation with eicosapentaenoic acid (EPA) in the treatment of pediatrics atopic dermatitis

Design
Single center, randomized, triple blind, phase III clinical trial with a parallel group design of 40 participants with atopic dermatitis equally divided in to two groups, EPA supplementation and placebo.

Settings and conduct
Children with atopic dermatitis refereed to Mofid hospital will be randomized to receive EPA supplementation or placebo. participants, healthcare providers, investigator and data analyst were all blinded.

Participants/Inclusion and exclusion criteria
Pediatrics patients aged 6 month to 13 years with atopic dermatitis included in this study. Exclusion criteria was age of more than 13 years and the extent of skin involvement less than 2% or more than 30% of the body's surface.

Intervention groups
Intervention group: EPA supplement is prescribed for 4 weeks. Control group: Placebo is prescribed for 4 weeks.

Main outcome variables
The variable of main outcome is the severity of eczema.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170608034390N2**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **retrospective**

Last update: **2019-01-27, 1397/11/07**
Update count: **0**

Registration date
2019-01-27, 1397/11/07

Registrant information

Name
Hadi Esmaily

Name of organization / entity
SBMU

Country
Iran (Islamic Republic of)

Phone
+98 21 8887 3704

Email address
esmaily_hadi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-05, 1397/02/15

Expected recruitment end date
2019-01-05, 1397/10/15

Actual recruitment start date
2018-05-05, 1397/02/15

Actual recruitment end date
2019-01-05, 1397/10/15

Trial completion date
2019-03-06, 1397/12/15

Scientific title
Evaluating the effect of eicosapentaenoic acid in the treatment of pediatric atopic dermatitis a randomized double-blind controlled trial

Public title
Eicosapentaenoic acid in the treatment of pediatric atopic dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pediatric patients with atopic dermatitis aged 6 months

to 13 years

Exclusion criteria:

Age greater than 13 years Extent of skin involvement less than 2% or more than 30% of the body surface Other skin problems other than atopic dermatitis

Age

From **6 months** old to **13 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

participants, healthcare providers, investigator, outcome assessors and data analyst and quality controller are blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Behesshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Taleghani Hospital, Shahid Arabi Ave, Yemen Ave, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-10-21, 1397/07/29

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.060

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20.8

ICD-10 code description

Other atopic dermatitis

Primary outcomes

1

Description

Severity of eczema

Timepoint

Measuring the severity of eczema at the beginning of the study (before the intervention) and 2 and 4 days after starting the drug.

Method of measurement

Based on a SCORing Atopic Dermatitis (SCORAD) Calculator

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: EPA supplement is given as 260 mg twice daily for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo is given as 260 mg twice daily for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Hadi Esmaieli

Street address

Mofid Children's Hospital, Shariati Ave.

City

Tehran
Province
Tehran
Postal code
1546815514
Phone
+98 21 2222 7021
Email
Esmaily_hadi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Taleghani Hospital, Shahid Arabi Ave, Yemen Ave, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hadi Esmaieli
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
Esmaily_hadi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hadi Esmailie
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
Esmaily_hadi@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahsa Moazami
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave.
City
Tehran
Province
Tehran

Postal code
1991953381
Phone
+98 21 8820 0118
Email
Esmaily_hadi@sbmu.ac.ir

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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The whole potential data is unpublished after being unidentifiable.
When the data will become available and for how long
Start the access period 6 months after printing the results.
To whom data/document is available
Researchers working in academic and industrial institutions.
Under which criteria data/document could be used
It can be used to carry out research work.
From where data/document is obtainable
Dr. Hadi Esmaeili, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences.
What processes are involved for a request to access data/document
Sending request is available.
Comments