

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of conjugated linoleic acid supplementation in improving of children pulmonary infection at 1-5 years old in Boali Hospital, Ardabil

Protocol summary

Summary

Objectives: Annually, respiratory infection diseases are those of the leading cause of deaths among children. Dietary supplements such as conjugated linoleic acid (CLA) are suggested for the treatment of respiratory infections. CLA supplements have several properties including antioxidant activity, anti-cancer, immune system regulation, anti-hypertensive, anti-diabetic and cholesterol reduction, that may be effect on improving respiratory infections in children. The purpose of study is the effect of CLA on improving the respiratory infections in children aged 1 - 5 years old. Design: Sixty children with acute respiratory infection aged 1- 5 years will be selected for study into two groups (30 test groups and 30 control groups). Setting and conduct: After obtaining consent from families, general information, anthropometric factors (height, weight and body mass index) and respiratory symptoms (including cough, fever, sore throat, and respiratory distress) will be collected and patient's appetite will also be tested. Participants including major eligibility criteria: Children with pulmonary infection aged 1-5 years old, in Buali Hospital, Ardabil. Those with malnutrition and chronic disease will be excluded. Intervention: Two grams of CLA supplement daily will be given to test group for two weeks. Main outcome measures (variables): Weight, body mass index and symptoms of respiratory infection were measured at the end of two weeks period, and then both groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402235144N6**

Registration date: **2014-07-20, 1393/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-20, 1393/04/29

Registrant information

Name

Ali Nemati

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 0052

Email address

a.nemati@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil, Iran.

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of conjugated linoleic acid supplementation in improving of children pulmonary infection at 1-5 years old in Boali Hospital, Ardabil

Public title

The effect of conjugated linoleic acid supplementation in improving of children pulmonary infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children with pulmonary infection in 1-5 years old; in Buali Hospital; Ardabil Exclusion criteria: Children with malnutrition and chronic disease

Age

From **93 years** old to **93 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Ardabil University of Medical Sciences

Street address

Ethic Committee of Ardabil University of Medical Sciences, Vice Chancellor for Research, Ardabil University of Medical Sciences, Dneshgah Avenue, Ardabil, Iran.

City

Ardabil

Postal code

5618985991

Approval date

2013-05-26, 1392/03/05

Ethics committee reference number

9107

Health conditions studied

1

Description of health condition studied

Children with lower respiratory tract infection.

ICD-10 code

J20, J21,

ICD-10 code description

Other acute lower respiratory infections

Primary outcomes

1

Description

Respiratory infection

Timepoint

At the end of treatment

Method of measurement

Signs and symptoms related to disease

Secondary outcomes

1

Description

Weight

Timepoint

At the beginning and after two weeks intervention

Method of measurement

Digital scales

2

Description

Body Mass Index

Timepoint

At the beginning and after two weeks intervention

Method of measurement

Stadiometers

3

Description

Appetite

Timepoint

At the beginning and two weeks after the intervention

Method of measurement

Questionnaire

4

Description

Cough

Timepoint

At the beginning and after two weeks intervention

Method of measurement

Questionnaire

5

Description

Fever

Timepoint

At the beginning and after two weeks intervention

Method of measurement

Questionnaire

6

Description

Sore throat

Timepoint

At the beginning and after two weeks intervention

Method of measurement

Questionnaire

7

Description

Respiratory distress

Timepoint

At the beginning and after two weeks intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Two grams of conjugated linoleic acid for 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: Was not given anything

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil University of Medical Science

Full name of responsible person

Ali Nemati

Street address

Nutrition Biochemistry Dept., Faculty of Medicine, Ardabil University of Medical Science, Daneshgah Avenue, Ardabil, Iran.

City

Ardabil

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Ardabil University of Medical Sciences

Full name of responsible person

Hadi Piri

Street address

Vice Chancellor for Research Ardabil University of Medical Sciences, Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil, Iran.

City

Ardabil

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research Ardabil 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

Ardabil University Of Medical Science

Full name of responsible person

Parisa Ahadi Kalkhoran

Position

Student

Other areas of specialty/work

Street address

Buali Hospital, Maidan Varzeh, Ardabil

City

Ardabil

Postal code

5613643197

Phone

+98 45 1771 3310

Fax

+98 45 1223 3055

Email

ali.nemati@arums.ac.ir

Web page address

www.arums.ac.ir

Sponsors / Funding sources

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Manoucher Barakl

Position

Specialization in MD

Other areas of specialty/work

Street address

Children Dept., Faculty of Medicine, Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil, Iran.

City

Ardabil

Postal code

5919711111

Phone

+98 45 1551 0052

Fax

+98 45 1551 0057

Email

m.barak@arums.ac.ir

Web page address

<http://www.arums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Ali Nemati

Position

Ph.D in Nutrition

Other areas of specialty/work

Street address

Nutritional Biochemistry Dept., Faculty of Medicine, Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil, Iran

City

Ardabil

Postal code

5619711111

Phone

+98 45 1551 0052

Fax

+98 45 1551 0057

Email

ali.nemati@arums.ac.ir

Web page address

<http://www.arums.ac.ir>

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