

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effects of probiotic supplementation and omega 3 on total antioxidant capacity in children and adolescents exposed to air pollutants: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Evaluation the effect of probiotic supplementation on total antioxidant capacity in healthy children and adolescents exposed to air pollution in Isfahan, Iran

Design

This study is a randomized, parallel, placebo-controlled, double-blind clinical trial. Participants will be allocated to treatment and omega3 groups by permuted block randomization with size of four. All participants and researchers will be blind to the treatment groups until the statistical analysis will be completed

Settings and conduct

The mean values of the 24-hour air quality index (AQI) in Isfahan city that register during the week before the day of blood sampling will be recorded. Among the air pollution measurement stations, one station will be selected randomly. From the schools located near that station, two of them are selected, and then 100 students who are eligible for the study will be invited to participate by random selection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study; healthy subject without any chronic disease, physiological disorders and endocrine diseases. Non-inclusion criteria: using antioxidant supplements other than supplements in this study; gastrointestinal problems; sensitivity to the supplements; taking any antioxidant supplements or probiotic products during the last month

Intervention groups

The intervention group will receive one probiotic supplement capsule called FamiLact (zist takhmir company, Tehran, Iran). Control group will receive 1000 mg omega 3 capsule daily.

Main outcome variables

Total antioxidant capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081105001434N12**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Roya Kelishadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 3060

Email address

kelishadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of probiotic supplementation and omega 3 on total antioxidant capacity in children and adolescents exposed to air pollutants: A randomized, double-blind, placebo-controlled trial

Public title

Effect of probiotic supplementation on total antioxidant capacities

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study's subjects who live in pollutant areas Healthy subject without any chronic disease, physiological disorders and endocrine disease

Exclusion criteria:

use of antioxidant supplements other than supplements selected during the study Gastrointestinal problems Sensitivity to the supplement under the study Taking any antioxidant supplements or probiotic products in the past month

Age

From **10 years** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method is used. Unit of randomization is individual. A random number table is used. The drugs are labeled A and B, and each person is randomly assigned to each group

Blinding (investigator's opinion)

Double blinded

Blinding description

Because this is a double-blind study, neither the participants nor the experimenters know who is consuming the drug and who is consuming the placebo. Subjects in both groups will be recruited on different days and will not see each other and will not understand the difference between drugs and the type of supplements that they use. The person who will give the supplements to the participants is not the researcher of the study. Also, all the supplements will be put in the same packaging and with the same label.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Isfahan University of Medical Sciences

Street address

Vice chancellor for research and technology; No 4 building; Isfahan University of Medical Sciences and Health Services; Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-03-05, 1398/12/15

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.791

Health conditions studied

1

Description of health condition studied

healthy subject exposed to air pollution

ICD-10 code

Z77.110

ICD-10 code description

Contact with and (suspected) exposure to air pollution

Primary outcomes

1

Description

Total antioxidant capacity

Timepoint

Before intervention and after intervention

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Height

Timepoint

before the intervention and after the intervention

Method of measurement

Meter

2

Description

Weight

Timepoint

before the intervention and after the intervention

Method of measurement

Scale

3

Description

Waist circumference

Timepoint

before the intervention and after the intervention

Method of measurement

Meter

4

Description

Body Mass Index

Timepoint

before the intervention and after the intervention

Method of measurement

weight (Kg)/ Squared meters

Intervention groups

1

Description

Intervention group: 1 FamiLact capsule (zist takhmir company, Tehran, Iran) will be consumed daily for 8 weeks . FamiLact ® is a synbiotic (probiotic + prebiotic) formulation and contains high amounts of 9 safe and beneficial bacterial strains plus fructooligosaccharides as prebiotic. Strains and prebiotic used include the following: • Lactobacillus rhamnosus• Lactobacillus casei• Lactobacillus bulgaricus• Lactobacillus acidophilus• Bifidobacterium breve• Bifidobacterium longum • Streptococcus thermophilus

Category

Prevention

2

Description

Control group will receive 1000 mg omega 3 capsule daily for 8 weeks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences

Full name of responsible person

Roya Kelishadi

Street address

Hezar Jarib street

City

Isfahan

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8163946711

Phone

+98 31 3792 5281

Email

roya.kelishadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Roya Kelishadi

Position

Professor

Latest degree

Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Roya Kelishadi, MD
Position
Professor
Latest degree
Specialist
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Person responsible for updating data

Contact

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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

Some part of the data, such as information about the main outcome can be shared

When the data will become available and for how long

2021

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Researchers in academic and scientific institutions when they need the data for meta-analysis study

From where data/document is obtainable

Send email to roya.kelishadi@gmail.com

What processes are involved for a request to access data/document

The applicant can request data and information from the corresponding person after providing a reason for having the data and how to use them

Comments