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 studys 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
Isfehan

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 interventi
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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