

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of probiotic supplementation and omega 3 on oxidative stress marker in healthy children and adolescents exposed to air pollutants: A Randomized, Double-Blind, Placebo-Controlled Trial

Protocol summary

Study aim

Assessment of the effect of probiotic supplementation on markers of oxidative stress 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 (four blocks). 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 will be recorded that register during the week before the day of blood sampling. Among the air pollution stations, one station will be selected randomly. two schools located near that station will be 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 are willingness to participate in the study, healthy subject without any chronic disease, physiological disorders and endocrine diseases. Subjects should not take any antioxidant supplements or probiotic products during the study and in the past month. Exclusion criteria are unwillingness to study, use of antioxidant supplements other than supplements selected , gastrointestinal problems or sensitivity to the supplement

Intervention groups

The treatment group will receive1 FamiLact capsules (zist takhmir company, Tehran, Iran) daily. Another group will receive 1000 mg omega 3 capsule daily

Main outcome variables

Plasma Malondialdehyde

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033747N3**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **prospective**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Motahar Heidari-Beni

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3320

Email address

motahar.heidari@nutr.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 oxidative stress marker in healthy children and adolescents exposed to air pollutants: A Randomized, Double-Blind, Placebo-Controlled Trial
Public title	Effect of probiotic supplementation on oxidative stress marker
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Willingness to participate in the study Healthy subject without any chronic physiological disorders and endocrine diseases Subjects should not take any antioxidant supplements or probiotic products during the study and in the past month Subjects that live in the pollutant areas
Exclusion criteria:	Unwillingness to continue study Use of antioxidant supplements other than supplements selected during the study Gastrointestinal problems or sensitivity to the supplement Failure to follow the intervention of the study
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	Simple randomization sampling will be used. A random number table will be used. The drugs will be labeled with A and B, and each person will randomly be assigned to one 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	Isfahan University of Medical Sciences
Street address	Vice chancellor for research and technology, Isfahan University of Medical Sciences and Health Services, Hezar Jerib Ave.
City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2020-01-05, 1398/10/15
Ethics committee reference number	IR.MUI.RESEARCH.REC.1398.792
Health conditions studied	
1	
Description of health condition studied	Healthy subjects expose to air pollution
ICD-10 code	Z77.110
ICD-10 code description	Contact with and (suspected) exposure to air pollution
Primary outcomes	
1	
Description	Plasma Malondialdehyde
Timepoint	Before the intervention and after the 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

The intervention group will consume 1 FamiLact capsules (zist takhmir company, Tehran, Iran) 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 are as the following:

- Lactobacillus rhamnosus
- Lactobacillus casei
- Lactobacillus bulgaricus
- Lactobacillus acidophilus
- Bifidobacterium breve
- Bifidobacterium longum
- Streptococcus thermophilus

Category

Prevention

2

Description

Control group will consume 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

Motahar Heidari-Beni

Street address

Hezar Jarib St., Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

8163946711

Phone

+98 31 3792 5284

Email

heidari.motahar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Motahar Heidari-Beni

Street address

Hezar Jarib St., Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

8163946711

Phone

+98 31 3792 5284

Email

heidari.motahar@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Motahar Heidari-Beni

Position

Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar Jarib St., Isfahan University of Medical Sciences
and Health Services
City
Isfahan
Province
Isfahan
Postal code
8163946711
Phone
+98 31 3792 5284
Email
heidari.motahar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Motahar Heidari-Beni
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar Jarib St., Isfahan University of Medical Sciences
and Health Services
City
Isfahan
Province
Isfahan
Postal code
8163946711
Phone
+98 31 3792 5284
Email
heidari.motahar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Motahar Heidari-Beni
Position

Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezarjrib street, Isfahan University of Medical
Sciences, Research Institute for Primordial Prevention
of Non-communicable Disease, Child Growth and
Development Research Center
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 5284
Email
heidari.motahar@gmail.com

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: heidari.motahar@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