

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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

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Isfahan

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#### **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**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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Assistant professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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of Non-communicable Disease, Child Growth and  
Development Research Center  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
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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: 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