

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effect of consuming low-fat vegetable butter enriched with resistant starch on the level of blood lipid factors, liver enzymes, and immune system function in 30-60 years adults - A Triple-blinded, randomized clinical trial

Protocol summary

Study aim

Investigating the consumption of vegetable butter containing resistant starch on the level of cholesterol, blood fat, blood sugar, liver enzymes and antibodies

Design

This study is conducted in the form of a parallel study including two control and intervention groups, blinded and randomized in the third phase. 70 people including two groups of 35 people will enter the study.

Randomization will be based on the lottery method.

Settings and conduct

This trial will be conducted in Alborz University of Medical Sciences, qualified people will be enrolled in the study and will be present in the study for six weeks. In this study, the appearance of butter with and without resistant starch is similar to each other, and the participants, the doctor, and the person who conducts the final evaluation are unaware of the type of butter received by the people, and only the main researcher of the project knows what type of butter each person has received.

Participants/Inclusion and exclusion criteria

People aged thirty to sixty with a body mass index below 30

Intervention groups

The control group will receive low-fat vegetable butter without resistant starch and the intervention group will receive low-fat vegetable butter containing resistant starch for six weeks.

Main outcome variables

Level of cholesterol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160117026069N8**

Registration date: **2023-12-03, 1402/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-03, 1402/09/12**

Update count: **0**

Registration date

2023-12-03, 1402/09/12

Registrant information

Name

Fereshteh Ansari

Name of organization / entity

Razi Vaccine and Serum Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 26 3405 0400

Email address

ansarif@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-29, 1402/09/08

Expected recruitment end date

2023-12-28, 1402/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of consuming low-fat vegetable butter enriched with resistant starch on the level of blood lipid factors, liver enzymes, and immune system function in 30-60 years adults - A Triple-blinded, randomized clinical trial

Public title

Effect of low-fat vegetable butter enriched with peribiotic on the level of blood lipid factors, liver enzymes, and immune system function

Purpose

Basic scienece

Inclusion/Exclusion criteria**Inclusion criteria:**

between 30-60 years old BMI below 30

Exclusion criteria:

History of hyperlipidemia History of high blood cholesterol Cardiovascular diseases Diabetes Liver diseases Kidney diseases Underlying and chronic diseases Allergy to vegetable butter Allergy to additives Digestive disorders

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

A number of 70 sealed envelopes, half of which contain code A and half contain code B, will be given to the participants to choose an envelope by lottery. People who choose package A will be given prebiotic butter and people who choose package B will be given normal butter. So the grouping of people will be random and the randomization list will not be predictable.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Prebiotic butter will be given to the intervention group and normal butter to the control group. The weight and appearance of both types of butter will be similar, and only the main researcher of the project will know which type of butter each person received. Other people, including the participant, the person who evaluates the health of the people, laboratory experts and the person doing the statistical analysis is unaware of which butter each person consumes.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Alborz university of medical sciences

Street address

Research deputy of Alborz medical science university,Saffarian Alley, Golshahr Blvd. Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2023-11-04, 1402/08/13

Ethics committee reference number

IR.ABZUMS.REC.1402.231

Health conditions studied**1****Description of health condition studied**

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

2**Description of health condition studied**

Hypercholesterolemia

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Hyperglycemia

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

High level of liver enzymes

ICD-10 code**ICD-10 code description****5****Description of health condition studied**

Level of Abs

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Total Cholesterol

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

Secondary outcomes

1

Description

HDL (High Density Lipoprotein) Cholesterol

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

2

Description

LDL (Low Density Lipoprotein) Cholesterol

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

3

Description

Triglyceride

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

4

Description

Serum Glutamic Oxaloacetic Transaminase (SGOT)

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

5

Description

Serum Glutamic Pyruvic Transaminase (SGPT)

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

6

Description

Alkaline Phosphatase (ALP)

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

7

Description

IgA

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

8

Description

IgM

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

9

Description

IgG

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

10

Description

HbA1C

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

11

Description

Fasting Blood Sugar (FBS)

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Use a lab kit

Intervention groups

1

Description

Control group: Daily consumption of 50 grams of low fat vegetable butter without resistant starch made by Mahgol factory for six weeks with each meal as desired by the participant

Category
Placebo

2

Description

Intervention group: Daily consumption of 50 grams of low fat vegetable butter enriched with resistant starch made by Mahgol factory for six weeks with each meal as desired by the participant

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alborz University of Medical Sciences
Full name of responsible person
Hadi Pourjafar
Street address
Research Deputy, Saffarian Alley, Golshahr Blvd,
Karaj
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3198764653
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+98 26 3464 3705
Email
pourjafarhadi59@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Behinehwazin Company
Full name of responsible person
Reyhaneh Ghaemi
Street address
No. 2, Parvaneh alley, next to Chamran highway, Jalal
Al Ahmad highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1439914173
Phone
+98 21 9109 9989
Email
info@behinehwazin.com
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**

Yes
Title of funding source
Behinehwazin Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hadi Pourjafar
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Food safety and Health
Street address
Vice-Chancellor for Research and Technology,
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**Person responsible for scientific
inquiries**

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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

All non-identifiable personal data of participants, study protocol, statistical analysis map, informed consent form, clinical study report, codes used in analysis, and data dictionary will be shared after the end of the study.

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

All researchers working in academic and scientific institutions and people working in the related industries.

Under which criteria data/document could be used

The data can be analyzed and used within the framework of the study protocol, but the right to publish the data will be with the research team, and if the data is published by other people, it is necessary to mention the source. People who wish to have access to data or documents should send their written request to Dr. Hadi Pourjafar's email and explain their reason for needing these data or documents and how they will use them. If a request with this theme is received, a decision will be made with the opinion of the research team and taking into account the job title of the applicant and the content of the written request sent by him.

From where data/document is obtainable

From the project manager, Dr. Hadi Pourjafar
pourjafarhadi59@gmail.com

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

The applicant must first submit a request including the requested data or document, the reason for the need for this data or document and the uses he will make of it along with a brief introduction of himself and his company or university to Mr. Hadi Pourjafar. After submitting the application to the project manager, this application will be reviewed at the earliest opportunity and within two weeks after receiving the application in a meeting with the presence of all those involved in the project. will be provided to the applicant.

Comments