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. 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)

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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

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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 Cholestrol
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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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
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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
he 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