Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The survey of oral supplementation effects with probiotic and alpha-lipoic acid, separately or in combination on the maintenance of weigh in overweight individuals under isocaloric weight loss diet

Protocol summary

Study aim

Determination of oral supplementation effects with probiotic and alpha-lipoic acid, separately or in combination on the maintenance of weigh in overweight individuals under isocaloric weight loss diet

Design

In this study, 88 people with over-weight who are eligible to enter the study are selected. Participants are randomly assigned to four intervention and control groups and each participant is assigned a code.

Settings and conduct

The present study is a randomized double blind clinical trial. Overweight people referred to the specialized clinic of Velayat hospital of Qazvin University of Medical Sciences are enrolled in this study. Then, 88 patients were selected and randomly divided into four intervention and control groups. In this study, the patient and researcher will be blinded to drugs and placebo

Participants/Inclusion and exclusion criteria

Willingness to cooperate, people with over weight, age range from 18 to 65 years, no acute or chronic metabolic disease, non pregnancy and breastfeeding

Intervention groups

First intervention group: the group receiving the iso-caloric diet with probiotic capsule, 500 mg per day; Second intervention group: the group receiving the iso-caloric diet with the lipoic acid capsule, 600 mg per day + probiotic capsule, 500 mg per day; Third intervention group: the group receiving the iso-calorie diet plus Lipoic acid capsule, 600 mg per day; Control group: the group receiving an iso-caloric diet plus a placebo capsule.

Main outcome variables

Weight, blood pressure, appetite, body fat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N10**
Registration date: **2018-12-16, 1397/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-20, 1398/07/28**
Update count: **1**

Registration date

2018-12-16, 1397/09/25

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 28 3375 2135

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-30, 1397/09/09

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of oral supplementation effects with probiotic and alpha-lipoic acid, separately or in combination on the maintenance of weigh in overweight individuals under isocaloric weight loss diet

Public title
Effect of probiotic and alpha-lipoic acid supplements on the maintenance of weigh in overweight individuals

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Overweight people according to WHO classification according to body mass index Age range from 18 to 65 years

Exclusion criteria:
Having an acute or chronic metabolic disorder

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
It will be done with simple random method using the lottery. For each patient, a number or code is provided, then the numbers will be written on pieces of paper. The pieces of paper are placed in a container and well stirred, and the sample is selected according to the sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients of both sexes will be randomly assigned to four intervention and control groups using a randomized distribution method. Supplements and a placebo placed in similar containers and encoded by someone other than the investigator, thus causing the patient and the investigator to be blinded to medicine and placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University Of Medical Sciences

Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Approval date
2018-11-10, 1397/08/19

Ethics committee reference number
IR.QUMS.REC.1397.183

Health conditions studied

1

Description of health condition studied
Simple obesity NOS

ICD-10 code
E66.9

ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Weight

Timepoint
Before the intervention and after the intervention

Method of measurement
Weight of the participants with minimal dress and no shoes to the nearest 0.5 kg using a medical weight scale

2

Description
Blood pressure

Timepoint
Before the intervention and after the intervention

Method of measurement
By medical barometer

3

Description
Appetite

Timepoint
Before the intervention and after the intervention

Method of measurement
Scale Analog Visual questionnaire

4

Description
Body fat

Timepoint

Before the intervention and after the intervention

Method of measurement

Using of Deurenberg equation

5

Description

C reactive protein

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

6

Description

Sleep quality

Timepoint

Before intervention and after intervention

Method of measurement

Petersburg’s sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: isocaloric diet based on the needs of the person with probiotic capsule, 500 mg per day for two months (Phase I of the study), probiotic capsule, 500 mg per day four months (Phase II study) Probiotic compounds: Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus, Manufacturer: zisttakhmir

Category

Treatment - Drugs

2

Description

Intervention group: isocaloric diet based on the needs of the person with lipoic acid capsule 600 mg per day+ probiotic capsule 500 mg per day for two months (Phase I of the study), lipoic acid capsule 600 mg per day with probiotic capsule 500 mg per day for four months (Phase II study) Probiotic compounds: Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus, Manufacturer: zisttakhmir

Category

Treatment - Drugs

3

Description

Intervention group: isocaloric diet based on the needs of the person with lipoic acid capsule 600 mg per day for two month (Phase I of the study), lipoic acid capsule 600 mg per day for four months (Phase II study)

Category

Treatment - Drugs

4

Description

Control group: isocaloric diet with placebo capsule for two month (Phase I of the study), placebo capsule for four months (Phase II study)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

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Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Peimani

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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Hossein Khadem Haghighian
Position
Faculty member
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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
Data on primary and secondary outcomes will be published.
When the data will become available and for how long
After completing the study and analyzing the data
To whom data/document is available
All researchers
Under which criteria data/document could be used

There is no objection to the use of data provided the source of the resource.

From where data/document is obtainable

IRCT site

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

Six months after the study

Comments