

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of supplementation synbiotic (probiotic bacteria *Lactobacillus plantarum* with chicory root extract) on antioxidant and inflammatory markers in overweight diabetics

Protocol summary

Summary

The aim of this study is to evaluate the effect of *Lactobacillus plantarum* with chicory root extract on antioxidant and inflammatory markers in overweight diabetic patients referred to the Research Center of Metabolic Disorders. This randomized controlled trial consists of 100 overweight diabetic patients, inclusions criteria: high blood sugar over 100 mg per dL, body mass index over 25 kg / m², the age between 20 and 75 years. After determining the population under study, patients were randomly divided into 4 groups : Symbiotic group: this group will receive a capsule containing *Lactobacillus plantarum* 108 cfu/ml and 2 g chicory root extract for 90 days, probiotics group: this group will receive a capsule containing *Lactobacillus plantarum* 108 cfu/ml, prebiotic group: this group will receive a capsule containing 2 grams chicory root extract and finally, control group: this group will received a capsule containing 2 grams of rice flour. At the end of the study to assess the inflammation, white blood cell count, hCRP, adiponectin and leptin, and to evaluate the antioxidant status, malondialdehyde and paraoxonase activity will be measured in the serum of patients will be measured. The results of each group will be compared with control and statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062628386N2**
Registration date: **2016-08-02, 1395/05/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-02, 1395/05/12

Registrant information

Name

Mahboobeh Mehrabani Natanzi

Name of organization / entity

Alborz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 6008

Email address

mahboobehmehrabani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Alborz University of Medical Sciences and Metabolic Disorders Research Center of Tehran University Of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation synbiotic (probiotic bacteria *Lactobacillus plantarum* with chicory root extract) on antioxidant and inflammatory markers in overweight diabetics

Public title

The effect of synbiotic supplement on improvement of diabetics overweight status.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: High blood glucose over 100 mg per deciliter, 20 to 75 years of age, voluntary consent for participation in the study
Exclusion criteria: A special diet (such as weight loss diet) in the previous three months of the study and during the study, patients with cancer, uncontrolled diabetes, acute infectious diseases, mental illness or any other illness that can potentially rapid decline weight, person with chronic gastrointestinal disease, using systemic antibiotic 6 weeks before entering the study, using probiotics and omega-3 supplements in the previous three months of the study, identified immunodeficiency, pregnancy or breastfeeding, Participation in other clinical trials in the last 6 months.

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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

Faculty of medicine, Golestan 1, Eshteraki,
Baghestan, Karaj

City

Karaj

Postal code

Approval date

2016-05-25, 1395/03/05

Ethics committee reference number

Abzums.Rec.1395.1

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Antioxidant biomarkers

Timepoint

3 months after intervention

Method of measurement

MDA concentration and PON activity in serum

2

Description

Inflammatory markers

Timepoint

3 months after intervention

Method of measurement

WBC counts, Leptin and Adiponectin concentration in serum and blood

3

Description

Fasting blood Glucose

Timepoint

At starting of the study and 3 months after intervention

Method of measurement

autoanalyzer

4

Description

Lipid profile

Timepoint

3 months after intervention

Method of measurement

autoanalyzer

Secondary outcomes

1

Description

weight

Timepoint

At starting of the study and after 3 months

Method of measurement

Scale

2

Description

Body mass index

Timepoint

At starting of the study and after 3 months

Method of measurement

Weight(Kg)/height(m²)

Intervention groups

1

Description

Intervention Group 1: Chicorium intybus. L powder 600 mg with probiotic bacteria L.plantarum 108 cfu/ml in capsule daily for 3 months

Category

Treatment - Drugs

2

Description

Intervention Group 2: Probiotic bacteria L.plantarum 108 cfu/ml in capsule daily for 3 months

Category

Treatment - Drugs

3

Description

Intervention Group 3: Chicorium intybus. L powder 600 mg in capsule daily for 3 months

Category

Treatment - Drugs

4

Description

Control Group: Two grams of rice flour in capsule daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes & Metabolic Diseases Clinic of Tehran
University Of Medical Sciences

Full name of responsible person

Dr Ensieh Nasli

Street address

North Kargar Street, Shahrivar Street, Diabetes &
Metabolic Diseases Clinic

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Alborz University of
Medical Sciences

Full name of responsible person

Dr Mohammad Javad Gharavi

Street address

Dara Building, East Pooneh, 45 meters Golshahr,
Karaj

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Alborz University of Medical
Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Metabolic Disorders Research Center of Tehran
University Of Medical Sciences

Full name of responsible person

Dr Maryam Razaghi Azar

Street address

North Kargar Street, Shahrivar Street, Diabetes &
Metabolic Diseases Clinic

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Metabolic Disorders Research Center of Tehran
University Of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

PhD in biochemistry

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty