# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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)

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+98 26 3433 6008

**Email address**
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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice Chancellor for Research of Alborz University of Medical SciencesandMetabolic 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
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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**

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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)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*