

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation the simultaneous effect of Probiotic (*Lactobacillus Acidophilus*) and Cinnamomum on glycemic index, lipid profile, antioxidant and inflammatory parameters in diabetic type 2 patients.

Protocol summary

Study aim

Determining the effect of consumption symbiotic supplement (*Lactobacillus Acidophilus* and Cinnamon) on lipid profile (LDL,HDL,CHOL,TG), inflammatory (TNF α , CRP), anti inflammatory(IL10), antioxidant factors and glycemic index in diabetic type 2 patients.

Design

In this research, 120 eligible diabetic type2 patients were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into one control and three intervention groups. This study is a double blind randomized clinical test. The randomization method is block randomization and random numbers table. Clinical trial phase:2-3

Settings and conduct

Setting: Preparing probiotic bacteria: at first, in laboratory, *Lactobacillus acidophilus* bacteria is cultured and after freez drying filled in the cap to 108 cfu (cap A). 0.5 grams Cinnamon powder is filled in the cap (cap B). 0.5 grams Rice flour is filled in another cap (cap C) as the placebo. Place of randomization is the clinic.The study is double blind. The person who put drugs in the cans and tags on them, person who select eligible patients, person who block and specify drug and placebo and the physician and the patients don't know about contents.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 25 to 65 years; Fasting blood sugar between 126 to 250 mg/dL; HbA1c less than 7.5; exclusion criteria: People who are younger than 25 years old and older than 65 years old; People with severe diabetes (The blood sugar more than 250); Women in pregnancy and lactation periods; People who consume special drugs (drugs which affect on blood sugar, such as corticosteroids, diuretics); Usage insulin, vitamin supplements and herbal; Change in diabetes medicine during last 6 months; People who don't tolerate lactose; Patients who have artificial heart valve; Patients with

short bowel syndrome; Patients with chronic liver, renal, lung, diseases and uncontrollable blood pressure; Patients with allergy; Patients with special diet or physical activity.

Intervention groups

group 1:This group receive a cap includes *Lactobacillus acidophilus* bacteria 108 cfu and a cap includes 0.5 grams cinnamon powder, daily in 90 days period.(cap A and cap B) *group 2:This group receive a cap includes *Lactobacillus acidophilus* bacteria 108 cfu and , daily in 90 days period.(cap A) *group 3:This group receive a cap includes 0.5 grams cinnamon powder, daily in 90 days period.(cap B) *group 4:This group receive a cap includes 0.5 grams rice flour powder, daily in 90 days period (cap C)

Main outcome variables

Lipid profile(total cholesterol,LDL, HDL,TG); Fasting blood sugar; HbA1C; IL10; TNF α ; CRP; Superoxide dismutase enzyme; Glutathione peroxidase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170305032883N2**
Registration date: **2018-02-09, 1396/11/20**
Registration timing: **retrospective**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Bahareh Tavakkolifar

Name of organization / entity

Alborz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Alborz University Of Medical Science

Expected recruitment start date

2016-07-20, 1395/04/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the simultaneous effect of Probiotic (Lactobacillus Acidulifilus) and Cinnamomum on glycemic index, lipid profile, antioxidant and inflammatory parameters in diabetic type 2 patients.

Public title

Effect of Probiotic and Cinnamomum in diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 25 to 65 years Fasting blood sugar between 126 to 250 mg/dl HbA1c less than 7.5

Exclusion criteria:

People who are younger than 25 years old and older than 65 years old People with severe diabetes (The blood sugar more than 250) Women in pregnancy and lactation periods People who consume special drugs (drugs which affect on blood sugar, such as corticosteroids, diuretics) Usage insulin, vitamin supplements and herbal Change in diabetes medicine during last 6 months People who don't tolerate lactose Patients who have artificial heart valve Patients with short bowel syndrome Patients with chronic liver , renal, lung, diseases and uncontrollable blood pressure Patients with allergy patients with special diet or physical activity Diabetic type2 patients who need to use insulin

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization we use, block randomization and random numbers table. In this rule, eligible patients have been divided to blocks with 4 or 6 members. We will get to half patients the numbers that first right digit of it, is even and to the others numbers that first right digit of it is odd, in the random numbers table. Then we will get to the half of patients (who have even numbers) herbal drug and to the others (who have odd numbers) placebo. Place of randomization is the clinic. Herbal drug and placebo is packed in the same package, except performer of Project, none has not information about it. Total of sample is 120 and patients will use drug packages randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization is double blind. The person who put drugs in the cans and tags on them, person who select eligible patients, person who block and specify drug and placebo and the physician and the patients don't know about contents.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Pharmaceutical Sciences Branch, Islamic Azad University

Street address

No. 99, Yasaman Alley, Yakhchal Street, Gholhak, Shariati Avenue, Tehran

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Province

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Postal code

194193311

Approval date

2017-05-15, 1396/02/25

Ethics committee reference number

IR.IAU.PS.REC.1396.74

2

Ethics committee

Name of ethics committee

Ethics committee of Alborz Univesity Of Medical Sciences

Street address

Alborz Univesity Of Medical Science, above Taleghani square, Azimiyeh, Karaj

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3149779453

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

abzums.rec.1394.92

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar (FBS)

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

Glucometer

2

Description

HbA1c

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

kit

3

Description

Superoxide dismutase enzyme

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

kit

4

Description

Glutathione proxidase

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

kit

5

Description

catalase

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

kit

6

Description

OxLDL

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

kit

7

Description

AOPP

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

laboratory

8

Description

AGEs

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

laboratory

9

Description

FRAP

Timepoint

Before intrvention and at the end of 3 month of beginning the research

Method of measurement

laboratory

10

Description

TG

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

Laboratory

11**Description**

Cholesterol

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

Laboratory

12**Description**

LDL

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

Laboratory

13**Description**

HDL

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

Laboratory

14**Description**

IL10

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

kit

15**Description**

TNF α

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

kit

16**Description**

CRP

Timepoint

Before intervention and at the end of 3 months of beginning the research

Method of measurement

Laboratory

Secondary outcomes**1****Description**

Side effects and liver toxicity

Timepoint

Within the research and until 1 month later

Method of measurement

Asking patients and observation if is needed

Intervention groups**1****Description**

Intervention group1: Capsule content of 0.5gr Cinnamomum and 10^8 colony per unit Lactobacillus Acidophilus, orally for 90 days

Category

Treatment - Drugs

2**Description**

Intervention group2: Capsule content of 10^8 colony per unit Lactobacillus Acidophilus, orally for 90 days

Category

Treatment - Drugs

3**Description**

Intervention group 3: One capsule orally per day content of 0.5gr cinnamomum powder

Category

Treatment - Drugs

4**Description**

Control group: Daily one capsule content of 0.5gr rice powder orally for 90 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Karaj diabetic clinic

Full name of responsible person

Maryam Sasani

Street address

No.134, Jamalpoor st., south Taleghani crossroad, karaj

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Sponsors / Funding sources

1

Sponsor

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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
Karaj 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
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Full name of responsible person
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Position
Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available