Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Evaluation the simultaneus effect of Probiotic (Lactobacillus Acidufilus) 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 (TNFα, 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; Chang e 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 live , 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 cholestrol,LDL, HDL,TG); Fasting blood sugar; HbA1C; IL10; TNFα; CRP; Superoxide dismutase enzyme; Glutathione proxidase

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

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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 simultaneus effect of Probiotic (Lactobacillus Acidufilus) 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 with4 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
City
Tehran
Province
Tehran
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
City
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Province
Alborz
Postal code
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 begining the research
Method of measurement
Glucometer

2

Description
HbA1c
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

3

Description
Superoxide dismutase enzyme
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

4

Description
Glutathione proxidase
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

5

Description
catalase
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

6

Description
OxLDL
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

7

Description
AOPP
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
laboratory

8

Description
AGEs
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
laboratory

9

Description
FRAP
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
laboratory

10

Description
TG

Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
Laboratory

11

Description
Cholesterol
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
Laboratory

12

Description
LDL
Timepoint
Before intrvention and at the end of 3 month of begining
Method of measurement
Laboratory

13

Description
HDL
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
Laboratory

14

Description
IL10
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

15

Description
TNFα
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
kit

16

Description
CRP
Timepoint
Before intrvention and at the end of 3 month of begining the research
Method of measurement
Laboratory

Secondary outcomes

1

Description
Side effects and liver toxicity
Timepoint
Within the reserch 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 Acidufilus, orally for 90 days
Category
Treatment - Drugs

2

Description
Intervention group2: Capsule content of 10^8 colony per unit Lactobacillus Acidufillus ,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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Karaj

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Email
Dayantebalborz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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dr.noorisepehr@gmail.com
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
Karaj University of Medical Sciences
Full name of responsible person
Bahareh Tavakolifar
Position
Associate professor
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Web page address

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