

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of Familact probiotic supplementation on lipid profile, glycemic control and insulin levels in patients with type 2 diabetes

Protocol summary

Summary

(1)Objectives: The effect of Probiotic supplements on some biochemical characteristics in patients with type 2 diabetes. (2)Design: Randomized Double blind clinical Trial. (3)Setting and conduct: The process of Balanced Block selection were performed until all the 60 patients were randomly divided into 2 groups. The first blood samples were taken from the subjects after assessing their anthropometric measurements and taking their 24 hour food recalls. Then, they were asked to consume either of the probiotic or placebo capsules for 6 weeks. Subjects were asked not to consume any probiotic-containing food, yogurt or its products during the intervention. More so, they were asked not to change their regular diet, activity and medicine during the study. Second Blood samples were also taken after an overnight fasting and before-after analysis was performed finally. (4)Participants including major eligibility criteria: (4-a) Major Inclusion Criteria: Patients with type 2 diabetes mellitus ; (4-b) Major Exclusion Criteria: Having replacement treatments like Hormone or supplemental vitamins ; tobacco and alcohol use ; clinical signs of some chronic or acute diseases. (5)Intervention: Group 1 (Intervention group) who daily received 2 capsules containing 1000 mg probiotic supplements after the lunch an donner meal, respectively , and Group 2 (Placebo group) who received placebo as the same, all for 6 weeks. (6)Main outcome measures (Variables): Fasting blood sugar, Serum insulin, Total Cholesterol, LDL-C, HDL-C, TG and HOMA-IR

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100714925N1**

Registration date: **2013-11-09, 1392/08/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-09, 1392/08/18

Registrant information

Name

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Name of organization / entity

Qazvin University of Medical Sciences, Department of Health

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Science and Shahid Beheshti Endocrine Research Center

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Familact probiotic supplementation on lipid profile, glycemic control and insulin levels in patients with type 2 diabetes

Public title

Effect of probiotic supplements on patients with type 2

diabetes

92.4.31, NO: 28.20.7651 ,Session 72

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having type 2 diabetes mellitus; the age range was 25 to 65 years with a fifteen-year maximal period of type 2 diabetes mellitus ; controlled glucose and lipid levels of the patients were considered ; taking drugs prescribed by doctors were permitted until their dosages were unchanged during the intervention. Exclusion criteria: Having replacement treatments like Hormone or supplemental vitamins ; tobacco and alcohol use ; clinical signs of chronic kidney, liver or pulmonary disease ; chronic or acute inflammatory disease (especially acute pancreatic inflammation and Endocarditis) ; heart valve disease ; short bowel syndrome ; allergies ; immunosuppressives ; pregnancy and lactation and taking less than 10% of probiotic or placebo supplements.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics Committe of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin, Iran

City

Qazvin

Postal code

Approval date

2013-07-10, 1392/04/19

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Baseline, and after 6 weeks

Method of measurement

Biochemical Analysis

2

Description

Serum Insulin

Timepoint

Baseline and after 6 weeks

Method of measurement

ELIZA

3

Description

HOMA-IR

Timepoint

Baseline and after 6 weeks

Method of measurement

Formula

4

Description

Lipid profile: Total cholesterol, Triglyceride, HDL-C, LDL-C

Timepoint

Baseline and after 6 weeks

Method of measurement

Biochemical Analysis

Secondary outcomes

1

Description

Dietary Factors

Timepoint

Baseline and after 6 weeks

Method of measurement

24 hour and 3-day dietary Recall

2

Description

Body Mass Index

Timepoint

Baseline and after 6 weeks

Method of measurement

Formula

3

Description

Waist Circumference

Timepoint

Baseline and after 6 weeks

Method of measurement

Inelastic Plastic Tape

4

Description

Hip Circumference

Timepoint

Baseline and after 6 weeks

Method of measurement

Inelastic Plastic Tape

5

Description

Waist to Hip Ratio

Timepoint

Baseline and after 6 weeks

Method of measurement

Formula

Intervention groups

1

Description

Intervention Group: Patients with type 2 Diabetes receive 2 Familact Probiotic Capsules twice per day (After lunch and after dinner), for 6 weeks. Each capsule contains 500 mg Probiotics which precisely consist of the following strains and species: Lactobasillus casei 3x10⁸ cfu/g Lactobasillus Acidofilus 2x10⁸ cfu/g Lactobasillus Bulgarigus 2x10⁹ cfu/g Lactobasillus rhamnosus 3x10⁸ cfu/g Bifidobacterium Breve 2x10⁸ cfu/g Bifidobacterium Longum 1x10⁹ cfu/g Streptococcus Thermophilus 3x10⁸ cfu/g

Category

Treatment - Drugs

2

Description

Placebo Group: Receiving 2 Placebo Capsules twice per day (after lunch and dinner), containing 1000 mg Magnesium Stearate for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Taleghani Hospital

Full name of responsible person

Elham Razmpoosh

Street address

Chamran Exp, Yemen street, Shahid Aerabi street, NO. 24

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Shahid Beheshti Endocrinology Research center

Full name of responsible person

Dr. Fereidoun Azizi

Street address

Chamran Exp, Yemen street, Shahid Aerabi street, NO. 24

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of Shahid Beheshti Endocrinology Research center

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

Vice chancellor of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Saeid Asef Zadeh

Street address

Qazvin University of Medical Sciences, Shadid Bahonar AVE, Qazvin, Iran

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Qazvin

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Qazvin 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 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