Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Maryam Javadi
Name of organization / entity
Qazvin University of Medical Sciences, Department of Health
Country
Iran (Islamic Republic of)
Phone
+98 28 3333 5367
Email address
mjavadi@qums.ac.ir

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

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

92.4.31, NO: 28.20.7651 ,Session 72

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 casaei 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 Streptococus 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
City
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
Name of organization / entity
Shahid Beheshti Endocrinology Research Center
Full name of responsible person
Dr. Parvin Mirmiran
Position
Associate Member, Department of Nutrition and Food Science, Shahid Beheshti University of Medical Sc
Other areas of specialty/work
Street address
Research Institute For Endocrine Sciences, NO. 24, Shahid Aerabi st, Yemen st, Chamran Exp
City
Tehran
Postal code
Phone
+98 21 2243 2500
Fax
Email
mirmiran@endocrine.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences and Shahid Beheshti Endocrinology Research Center
Full name of responsible person
Elham Razmpoosh
Position
MSc Student of Health Science in Nutrition
Other areas of specialty/work
Street address
Research Institute For Endocrine Sciences, NO. 24, Shahid Aerabi st, Yemen st, Chamran Exp
City
Tehran
Postal code
Phone
+98 21 2243 2500
Fax
Email
Elhamrz88@yahooo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Nutrition and Food Science, Qazvin University of Medical Sciences
Full name of responsible person
Dr. Maryam Javadi
Position
Assistant Member, Department of Nutrition and Food Science, Qazvin University of Medical Science
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences, Shahid Bahonar AVE, Qazvin, Iran
City
Qazvin
Postal code
3419759811
Phone
+98 28 1334 1934
Fax
+98 28 1334 1934
Email
mjavadi@qums.ac.ir
Web page address

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