Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Effects of synbiotic Gaz on fasting plasma glucose and lipid profiles of diabetic subjects

Protocol summary

Study aim

Objective: The effect of probiotic Gaz enriched with inulin on the biochemical parameters including fasting plasma glucose, lipid profiles, inflammatory factors and stress oxidative in patients with type 2 diabetes.

Design

Study design: Randomized cross-over double-blind controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive synbiotic (n=35) or control (n=35).

Settings and conduct

Among patients with type 2 diabetes mellitus referred to Gholabchi outpatient Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 70 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Synbiotic and control are similar in shape and size. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. At the beginning and the end of the intervention: 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with type 2 diabetes mellitus aged 35 to 70 years. Exclusion Criteria: Pregnant, using insulin or vitamin supplements, liver and inflammatory diseases, coronary heart disease, allergies, short bowel syndrome.

Intervention groups

Intervention group: Probiotic viable and heat-resistance strain Lactobacillus sporogenes (107 CFU), 0.04 g inulin, 0.38 g isomalt, 0.36 g sorbitol, 0.05 g stevia per 1 g, 9 g, thrice a day for 6 weeks. Control group: 0.38 g isomalt, 0.36 g sorbitol, 0.05 g stevia per 1 g, 9 g, thrice a day for 6 weeks.

Main outcome variables

Outcomes: Inflammatory factor and calcium (primary outcome), and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201201195623N1**
Registration date: **2012-02-12, 1390/11/23**
Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**
Update count: **1**

Registration date

2012-02-12, 1390/11/23

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University Of Medical Science and Sekkeh Gaz (Isfahan)

Expected recruitment start date

2010-08-21, 1389/05/30

Expected recruitment end date

2010-09-21, 1389/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of synbiotic Gaz on fasting plasma glucose and lipid profiles of diabetic subjects

Public title
Effects of probiotic Gaz enriched with Inolin in diabetes treat
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes mellitus aged 35 to 70 years
Exclusion criteria:
Pregnant Using insulin or vitamin supplements Liver and inflammatory diseases Coronary heart disease Allergies Short bowel syndrome
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qom University Of Medical Science
Street address
Sahelli Bolvar
City
Qom
Province
Ghoum
Postal code
3715614566
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
91288

Health conditions studied

1

Description of health condition studied
diabetes- cardiovascular
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Hs-CRP
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Elisa

2

Description
Calcium
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Elisa

2

Description
Insulin resistance

Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Questionnaire

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
HDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Total antioxidant
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Glutathione
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Liver enzymes
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
Magnesium
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Iron
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

11

Description
Systolic blood pressure
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Manometer

12

Description
Diastolic blood pressure
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Manometer

13

Description
LDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

14

Description
Uric acid
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

15

Description
Bilirubin
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Probiotic viable and heat-resistance strain Lactobacillus sporogenes (107 CFU), 0.04 g inulin, 0.38 g isomalt, 0.36 g sorbitol, 0.05 g stevia per 1 g, 9 g, thrice a day for 6 weeks.
Category
Treatment - Other

2

Description
Control group: 0.38 g isomalt, 0.36 g sorbitol, 0.05 g stevia per 1 g, 9 g, thrice a day for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golabchi diabetes Clinic, Kashan
Full name of responsible person
Faraji
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
faraji-ma@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University Of Medical Science
Full name of responsible person
Dr Alireza Kohpeimaie
Street address
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Postal code
3715614566
Phone
+98 25 3784 2227
Email
Kohpeimaie-a@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University Of Medical Science
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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

Contact
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Associate professor
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Ph.D.
Other areas of specialty/work
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Fax
Email
asemi_za@yahoo.com
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