

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

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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 Inulin 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

Ghous

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 Rajaei Avenue, Kashan

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Isfahan

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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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3715614566

Phone

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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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Full name of responsible person

Zatollah Asemi

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Latest degree

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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

Person responsible for updating data**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

Street address