

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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 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

##### City

Kashan

##### Province

Isfahan

##### 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

Sahelli Bolvar

##### City

Qom

##### Province

Ghous

##### 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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Ghotbe Ravandi Boulevard, Kashan

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asemi\_r@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kashan University Of Medical Science

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Postal code**

8115187159

**Phone**

+98 36 1446 3378

**Fax****Email**

asemi\_z@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

**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**