Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effects of a synbiotic food of fortified with beta-carotene on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in patients with type 2 diabetes mellitus

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of a synbiotic food of fortified with beta-carotene on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in patients with type 2 diabetes mellitus.

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=25) or control (n=26).

Settings and conduct

Among patients with type 2 diabetes mellitus referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 51 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.

Intervention groups

Intervention group: Probiotic viable and heat-resistance strain Lactobacillus sporogenes (107 CFU), 0.1 g inulin, 0.38 g isomalt, 0.36 g sorbitol, 0.05 g stevia, 0.05 g beta-carotene 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: Insulin (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: **IRCT201301195623N5**
Registration date: **2013-02-23, 1391/12/05**
Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**
Update count: **1**

Registration date

2013-02-23, 1391/12/05

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

Kashan University of Medical Science and Sekkeh Gaz company

Expected recruitment start date

2013-02-12, 1391/11/24

Expected recruitment end date

2013-02-15, 1391/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of a synbiotic food of fortified with beta-carotene on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in patients with type 2 diabetes mellitus

Public title

The effects of a synbiotic food of fortified with beta-carotene in the treatment of diabetes

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

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: **51**

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

Kashan University of Medical Science

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2013-02-11, 1391/11/23

Ethics committee reference number

29/5/1/4138/پ

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

Insulin

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Elisa

Secondary outcomes

1

Description

Insulin resistance

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Questionnaire

2

Description

Triglycerides

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

3

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

4

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

5

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

6

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

7

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

8

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

9

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

10

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

11

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

12

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

13

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

14

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

15

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

Method of measurement
Manometer

16

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

17

Description
VLDL
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), 0.1 g inulin, 0.38 g isomalt, 0.36 g sorbitol, 0.05 g stevia, 0.05 g beta-carotene per 1 g, 9 g, thrice a day for 6 weeks.
Category
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
Naghavi outpatient Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Science
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
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Person responsible for updating data

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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