Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of daily consumption of probiotic yogurt on albumin to creatinine Ratio, eGFR and metabolic parameters in type 2 diabetic patients with microalbuminuria

Protocol summary

Study aim

If appropriate, it is recommended to use probiotic yogurt in the diet of patients with type 2 diabetes with nephropathy

Design

Controlled, parallel, double-blind clinical trial, people with diabetic nephropathy, 60 people; randomization by rand function of Excel software

Settings and conduct

Controlled, parallel, double-blind clinical trial, in Imam Khomeini Hospital Diabetes Clinic, before the intervention, anthropometric assessments, glycemic indexes, renal indices, blood lipid indices, inflammatory markers and blood pressure indices in all individuals are assessed. The software will randomly divide participants into intervention and control groups; intervention: 300 g daily probiotic yogurt for 8 weeks, control: 300 g normal yogurt daily for 8 weeks. The yogurts have the same color, shape, taste and smell are used so that the researcher and the patient are not aware of its type and only our distributor is aware of its type.

Participants/Inclusion and exclusion criteria

Inclusion: Diabetic nephropathy with microalbuminuria (Albumin to creatinine ratio 30-299 mg / g Cr, eGFR≥ 30 ml / min / 1.73m2), age 20 to 80 years, BMI less than 40 kg / m2 Exclusion: History of chronic diseases including: IBD, liver disease, rheumatoid arthritis, renal disorders other than diabetic nephropathy, smoking and alcohol and tobacco use, history of antibiotics and NSAIDs during a recent month, use Omega-3 supplementation and vitamins E, C during the last three months, taking probiotic supplements or foods containing probiotics during the last three months, lactose intolerance, pregnancy

Intervention groups

Intervention: daily 300g probiotic yogurt for 8 weeks, control: 300g normal yogurt for 8 weeks

Main outcome variables

eGFR; Albumin to creatinine ratio; Urea; Creatinine; Serum uric acid; Systolic and diastolic blood pressure; TG; TC; LDL; HDL; HbA1c; Fasting blood sugar; hs-CRP; Weight; Waist; BMI

General information

Reason for update

Replacement of albumin to creatinine ratio index due to newer, higher accuracy and ease of measurement

Acronym

IRCT registration information

IRCT registration number: **IRCT20201125049491N1**
Registration date: **2020-12-28, 1399/10/08**
Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**
Update count: **2**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

Seyed Mojtaba Ghoreishy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4222 8244

Email address

seyed.mojtaba.ghoreishy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date
2021-12-11, 1400/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of daily consumption of probiotic yogurt on albumin to creatinine Ratio, eGFR and metabolic parameters in type 2 diabetic patients with microalbuminuria

Public title
The effect of daily consumption of probiotic yogurt on albumin to creatinine Ratio, eGFR and metabolic parameters in type 2 diabetic patients with microalbuminuria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic nephropathy with microalbuminuria (Albumin to creatinine ratio 30-299 mg / g Cr, eGFR≥ 30 ml / min / 1.73m2) Has an age of 80-20 years BMI less than 40 kg / m2
Exclusion criteria:
History of chronic diseases including: IBD, liver disease, rheumatoid arthritis, renal disorders except diabetic nephropathy Smoking, alcohol and tobacco History of taking antibiotics and NSAIDS (during the last month) Take omega 3 supplements and vitamins E and C during the last three months Consumption of probiotic supplements or foods containing probiotics during the last three months Lactose intolerance Pregnancy
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Each person is assigned a code and this code is entered into Excel software, and then used to randomize the rand function of Excel software.
Blinding (investigator's opinion)
Double blinded
Blinding description
The shape, appearance, packaging, color and smell of both probiotic and non-probiotic yogurts will be quite similar. In addition, the person who provides yogurts to patients is aware of the type of yogurt, but the researcher and the patient are not aware of it.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
First Floor, Faculty of Medicine, Building No. 1, North Door of the University, POURSINA St, GHODS St, ENGHELAB St
City
Tehran
Province
Tehran
Postal code
14155-6117
Approval date
2020-09-19, 1399/06/29
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.458

Health conditions studied

1

Description of health condition studied
Diabetic nephropathy
ICD-10 code
E11.21
ICD-10 code description
Type 2 diabetes mellitus with diabetic nephropathy

Primary outcomes

1

Description
Albumin to creatinine ratio
Timepoint
First the intervention and 8 weeks later at the end of the intervention
Method of measurement
Laboratory kits

Secondary outcomes

1

Description
eGFR
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

2

Description
TG
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

3

Description
TC
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

4

Description
LDL
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

5

Description
HDL
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

6

Description
FBS
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

7

Description
HbA1c
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

8

Description
hs-CRP
Timepoint
At the beginning of the intervention and 8 weeks later at the end of the intervention
Method of measurement
Special laboratory kit

Intervention groups

1

Description
Intervention group: They will receive 300g of probiotic yogurt(Haraz Company) enriched with Bifidobacterium lactis and Lactobacillus acidophilus strains daily for 8 weeks. Microbiological analyzes showed that the average colony content of both strains is 10 ^ 6 CFU / g.
Category
Rehabilitation

2

Description
Control group: Control group: 300g will receive normal yogurt from Haraz company for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Imam Khomeini Hospital, Tehran
Full name of responsible person
Seyed Mojtaba Ghoreishy
Street address
Imam Khomeini Hospital, at the end of Keshavarz Boulevard, Dr. Gharib Street, Tehran, Tehran Province
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mr. Dr. Sahraian

Street address
Vice Chancellor for Research and Technology, Central University Organization, sixth floor, corner of Quds Street, Keshavarz Boulevard

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Tehran

Postal code
14155-6117

Phone
+98 21 8163 3685

Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Diabetes Research Center, Research Institute of Endocrinology and Metabolism, Tehran University of Medical Sciences

Proportion provided by this source
40

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
Tehran University of Medical Sciences

Full name of responsible person
Seyed Mojtaba Ghoreishy

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Faculty of Nutrition and Dietetics, No. 44, Hojjatdoost Alley, Naderi St., Keshavarz Boulevard

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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