Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

"The effect of probiotics and curcumin on glycemic and insulin status and oxidative stress in patients with type 2 diabetes: a triple-blind clinical trial"

Protocol summary

Study aim
Determining the effect of probiotic and curcumin supplementation on insulin status and glycemic indices in patients with type 2 diabetes

Design
A clinical trial with a control group, parallel groups, triple blind, randomized on 92 patients.

Settings and conduct
The study will be conducted in a triple-blind (patient, therapist, and analyst) design at Imam Khomeini Hospital. The subjects' dietary intake will be assessed using a 24-hour food recall. Body composition, variables of interest, and 24-hour food recall questionnaires and the International Physical Activity Score will be assessed before and after the intervention. Nutrient analysis will be performed using N4 software.

Participants/Inclusion and exclusion criteria
Inclusion criteria included age between 30 and 65 years, patients with type 2 diabetes; BMI between 25 to 35 kg/m2; HbA1C between 6.5% and 9%; no use of vitamin, mineral or antioxidant and pro- and pre-supplements in the past month; and stable medical condition. Exclusion criteria included; having or having comorbidities, pregnancy or breastfeeding; insulin injection; history of sensitivity to probiotics, turmeric or curcumin; occurrence of gastrointestinal problems caused by the intervention; use of antibiotics in the 14 days before the start of the intervention; and unwillingness to continue the study.

Intervention groups
The probiotic group will receive daily probiotic supplement with a dose of 10^9 CFU (Zist Takhmir Company) along with a curcumin placebo; the curcumin group will consume one daily 500 mg curcumin capsule (Karen Company) along with a probiotic placebo; the curcumin and probiotic combination group will receive one daily probiotic capsule along with one 500 mg curcumin capsule for 8 weeks. the control group will receive the placebo corresponding to both supplements.

Main outcome variables
Insulin status and glycemic indices in patients with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191105045340N7**
Registration date: **2025-07-22, 1404/04/31**
Registration timing: **prospective**

Last update: **2025-07-22, 1404/04/31**
Update count: **0**

Registration date
2025-07-22, 1404/04/31

Registrant information

Name
Seyedeh Tayebeh Rahideh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8670 4843

Email address
rahide.t@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-01, 1404/06/10

Expected recruitment end date
2026-04-30, 1405/02/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"The effect of probiotics and curcumin on glycemic and insulin status and oxidative stress in patients with type 2 diabetes: a triple-blind clinical trial"

Public title
The effect of probiotics and curcumin in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: Patients between 30 and 65 years. Diagnosis of type 2 diabetes: Patients with type 2 diabetes who have had the disease for at least 6 months and have been confirmed by an endocrinologist Body mass index (BMI) in the range of 25 to 35 kg/m2.4. HbA1C range between 6.5% and 9% No supplements: No use of vitamin, mineral or antioxidant supplements and pro- and pre-supplements in the past month. Stable medical condition: Patients who have a stable medical condition and their main medications have not changed in the past month.
Exclusion criteria:
Comorbidities: Severe renal, hepatic, cardiovascular, cancer, or other disorders. Insulin injections Pregnant or breastfeeding women. Allergy to interventions: History of allergy to probiotics, turmeric, or curcumin. Occurrence of digestive problems due to the intervention (including reflux) Use of antibiotics in the 14 days prior to the start of the intervention Unwillingness to continue the study: voluntary withdrawal of the patient or failure to cooperate in taking supplements or providing samples.
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of dividing participants into different groups is as follows: after meeting the conditions, participants are randomly divided into four groups A, B, C and D. This division is done using the random block method. To generate the random sequence in this trial, the random block method with a fixed or variable block size is used to ensure equal distribution of participants in the groups. The sequence of allocation of participants is generated using specialized software such as Random Allocation Software or statistical packages such as STATA or R (blockrand function in R). The resulting sequence is stored in an encrypted file and will be maintained and executed by an independent person who is not involved in the data collection process. Drug companies will be responsible for manufacturing placebos, which are similar in appearance to the drugs, and they will also be asked to randomly place the letters A or B on the drug or placebo and the other letter on the other.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This interventional study will be conducted in a triple-blind manner. Blinding will include the patient, therapist, and analyst. Drug companies will manufacture placebos that are identical in appearance to the drugs and will also be asked to randomly label one drug or placebo with the letter A or B and the other with the letter B. The type of drug and placebo will be kept confidential until the end of the data analysis. After the analysis, the researcher will ask the drug manufacturer for the type of labels. This means that the therapist will not know whether the drug or placebo is in the drug package. The patient and analyst will also not be aware of this. The placebo capsules will be identical in appearance, color, and smell to the capsules in the intervention group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Public Health -Iran University of Medical Sciences
Street address
Management of Research Development and Evaluation, Deputy of research and technology, next to Milad Tower, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-06-09, 1404/03/19
Ethics committee reference number

IR.IUMS.SPH.REC.1404.001

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood sugar (FBS) level
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Blood test

2

Description
Serum insulin
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Blood test

Secondary outcomes

1

Description
Malondialdehyde level
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Blood test

2

Description
Total antioxidant capacity (TAC)
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Blood test

3

Description
HbA1c
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Blood test

4

Description
Homeostatic insulin resistance index (HOMA-IR)
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Calculated from fasting glucose and insulin levels using the formula (Fasting Glucose (mg/dL) * Fasting Insulin (mU/L)) / 405

Intervention groups

1

Description
Intervention group: They receive one daily probiotic supplement capsule with a dose of 109 CFU (Zist Fermentation Company) (Food and Drug Supplement IRCT code: 5299398045382901) along with a curcumin placebo;
Category
Treatment - Other

2

Description
Intervention group: They take one 500 mg capsule of curcumin (Karen Company) (IRCT code is 1058067011726337) daily along with a probiotic supplement;
Category
Treatment - Other

3

Description
Intervention group: They receive one probiotic capsule daily along with one 500 mg curcumin capsule.
Category
Treatment - Other

4

Description
Control group: Will receive placebo for both supplements
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Seyedeh Tayebeh Rahideh
Street address
end of Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Fax
+98 21 6658 1625
Email
Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Safa
Street address
The Headquarters of University, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
info@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
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
Iran University of Medical Sciences
Full name of responsible person
Seyedeh Tayebeh Rahideh
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4843
Fax
Email
rahide.t@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyedeh Tayebeh Rahideh
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4843
Fax
Email
rahide.t@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyedeh Tayebeh Rahideh
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4843
Fax
Email
rahide.t@iums.ac.ir

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