Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Effects of Inositol Supplementation on inflammatory status, oxidative stress, fatigue, and insulin resistance and lipid profile in type 2 diabetic patients with chronic kidney disease: Double-blind randomized clinical trial (RCT)

Protocol summary

Study aim

To evaluate the effect of inositol supplementation on inflammation, oxidative stress, fatigue, insulin resistance, and lipid profile in patients with type 2 diabetes and chronic kidney disease.

Design

A randomized, double-blind, placebo-controlled, parallel trial will be conducted on 48 patients with type 2 diabetes and CKD stages 3–4. After a two-week run-in, participants will be allocated to inositol and placebo groups using stratified block randomization by age and sex (blocks of four). The intervention lasts 8 weeks.

Settings and conduct

This study will be conducted in Shariati and Shohadaye Tajrish kidney clinics, Tehran. After convenience sampling and consent, participants will complete two-week run-in and baseline assessment, then be randomly allocated to intervention/control groups to receive inositol or placebo for 8 weeks. Participants, investigators, and outcome assessors will be blinded; supplements will be similar and coded.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes and CKD stage 3–4 before dialysis, aged 20–60 years, BMI 20–30 kg/m², and willing to participate will be included. Individuals with glucocorticoid, antibiotic, fluvoxamine, NSAID, or warfarin use, smoking, recent hospitalization, autoimmune/thyroid diseases, malignancies, antioxidant use, pregnancy, planned pregnancy, or breastfeeding will be excluded.

Intervention groups

After run-in, participants will be randomly allocated to intervention and control groups. The inositol group will receive 1600 mg/day (two 800 mg supplements), and the control group placebo. Both groups will maintain dietary intake, physical activity, and medication regimen. The intervention lasts 8 weeks.

Main outcome variables

Inflammatory markers (IL-6 and TNF-α); oxidative stress (MDA and TAC); fatigue; insulin resistance (HOMA-IR, QUICKI, and TyG); lipid profile (TG, TC, LDL, and HDL)

General information

Reason for update

Acronym

INS-CKD

IRCT registration information

IRCT registration number: **IRCT20170202032367N14**

Registration date: **2026-09-07, 1405/06/16**

Registration timing: **prospective**

Last update: **2026-09-07, 1405/06/16**

Update count: **0**

Registration date

2026-09-07, 1405/06/16

Registrant information

Name

Hossien Imani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01
Expected recruitment end date
2027-03-20, 1405/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effects of Inositol Supplementation on inflammatory status, oxidative stress, fatigue, and insulin resistance and lipid profile in type 2 diabetic patients with chronic kidney disease: Double-blind randomized clinical trial (RCT)

Public title
The Effect of Inositol Supplementation on Inflammation, Fatigue, and Metabolic Status in Patients with Type 2 Diabetes and Chronic Kidney Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age >20 and <60 years. Body mass index (BMI) >20 and <30 kg/m². Willingness to participate in the study. Pre-dialysis chronic kidney disease (CKD) stage 3 or 4, diagnosed based on laboratory findings and confirmed by a nephrologist.
Exclusion criteria:
Use of glucocorticoids, antibiotics, fluvoxamine, non-steroidal anti-inflammatory drugs (NSAIDs), or warfarin. Current cigarette smoking. History of hospitalization within the past 3 months. History of any autoimmune diseases, thyroid disorders, or malignancies. Use of antioxidant supplements within the past 3 months. Pregnancy, intention to become pregnant, or breastfeeding within the next 2 months.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
After completion of the run-in period and baseline assessments, eligible participants will be randomly allocated to the intervention and control groups. Stratified block randomization will be used for allocation. The unit of randomization will be the individual participant. Participants will first be stratified according to sex (male/female) and age, and then within each stratum, they will be randomly assigned to the intervention group (inositol supplementation) or control group (placebo) using blocks of four. The random allocation sequence will be generated using statistical software. Group allocation will remain concealed from investigators and participants until the initiation of the intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind clinical trial. Participants, investigators, care providers, and outcome assessors will be blinded to the group allocation. The inositol supplement and placebo will be identical in appearance, packaging, and administration method. To maintain blinding, the supplements and placebo will be coded by an individual who is not involved in participant assessment or data analysis. Participants will not be informed whether they receive inositol supplementation or placebo during the study period. Individuals responsible for intervention delivery, data collection, clinical and laboratory assessments, and outcome evaluation will remain unaware of participants' group assignments. The allocation codes will remain concealed from investigators and data analysts until completion of data collection and final statistical analysis. The codes will be revealed after completion of the final analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Dr. Shariati Educational, Research and Therapeutic Center – Tehran University of Medical Sciences (R
Street address
No. 44, Hojatdoost Alley, Naderi Street, Keshavarz Boulevard, Tehran, Iran – Department of Clinical Nutrition, 5th Floor, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences
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Province
Tehran
Postal code
1417613151
Approval date
2026-09-03, 1405/06/12

Ethics committee reference number
IR.TUMS.SHARIATI.REC.1405.088

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

2

Description of health condition studied
Chronic kidney disease, stage 3
ICD-10 code
N18.3
ICD-10 code description
Chronic kidney disease, stage 3 (moderate)

3

Description of health condition studied
Chronic kidney disease, stage 4
ICD-10 code
N18.4
ICD-10 code description
Chronic kidney disease, stage 4 (severe)

Primary outcomes

1

Description
Changes in tumor necrosis factor alpha level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of tumor necrosis factor alpha level using a specific laboratory assay kit

2

Description
Changes in interleukin 6 level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of interleukin 6 level using a specific laboratory assay kit

3

Description
Changes in total antioxidant capacity
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of serum total antioxidant capacity using a laboratory method and commercial assay kit

4

Description
Changes in malondialdehyde level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of serum malondialdehyde level using a laboratory method and commercial assay kit

5

Description
Changes in fatigue score
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Assessment of fatigue using the Fatigue Assessment Scale questionnaire

6

Description
Changes in triglyceride glucose index
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Calculation of triglyceride glucose index based on laboratory measurements of triglycerides and fasting blood glucose

7

Description
Changes in insulin resistance index
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Calculation of insulin resistance index based on fasting blood glucose and fasting insulin

8

Description
Changes in insulin sensitivity index
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Calculation of insulin sensitivity index based on fasting blood glucose and fasting insulin

9

Description
Changes in fasting blood glucose level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of fasting blood glucose using a standard laboratory method

10

Description
Changes in fasting insulin level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of fasting insulin level using a specific laboratory assay kit

11

Description
Changes in total cholesterol level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of serum total cholesterol using a standard laboratory method

12

Description
Changes in triglyceride level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of serum triglyceride using a standard laboratory method

13

Description
Changes in low-density lipoprotein level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of serum low-density lipoprotein using a standard laboratory method

14

Description
Changes in high-density lipoprotein level
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of serum high-density lipoprotein using a standard laboratory method

Secondary outcomes

1

Description
Changes in systolic blood pressure
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of systolic blood pressure using a standard blood pressure monitor

2

Description
Changes in diastolic blood pressure
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of diastolic blood pressure using a standard blood pressure monitor

3

Description
Changes in body weight
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Measurement of body weight using a standard scale

4

Description
Changes in body mass index
Timepoint
At baseline (before intervention) and after 8 weeks of intervention
Method of measurement
Calculation of body mass index based on measured body weight and height

5

Description
Changes in dietary intake
Timepoint
At baseline, week 4, and end of week 8 of intervention
Method of measurement
Assessment of dietary intake using 24-hour dietary recalls including two non-holiday days and one holiday

6

Description
Changes in physical activity level
Timepoint
At baseline, week 4, and end of week 8 of intervention

Method of measurement
Assessment of physical activity level using a physical activity questionnaire

Intervention groups

1

Description
Participants in the intervention group will receive the IP-6 product (Inositol Hexaphosphate) marketed under the brand name M Plus IP-6. Each tablet contains 800 mg of inositol hexaphosphate. Participants will take two tablets daily, equivalent to 1,600 mg per day, for 8 weeks. The product will be administered according to the study protocol. This product is manufactured under the M Plus brand and is commercially available in Iran.
Category
Treatment - Other

2

Description
Participants in the control group will receive a placebo identical in appearance, color, and packaging to the intervention product but containing no active ingredient (inositol hexaphosphate). The placebo will be administered in the same manner as the intervention, with participants taking two tablets daily in two divided doses (morning and evening) for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Hossein Imani
Street address
Tehran, North Kargar Street, Jalal Al-Ahmad Intersection, Opposite the Faculty of Economics, Shariati Hospital
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kurdi
Street address
Keshavarz Blvd., corner of Quds St., Central Organization of the University, 6th floor of Research and Technology Vice-Chancellor
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141765383761
Phone
+98 21 8163 3698
Email
Vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Hossein Imani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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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
Due to the confidentiality of participants' clinical and personal information and adherence to ethical research principles, individual participant data will not be shared.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available