Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of advanced glycation end-products restricted diet and combined supplementation of zinc, pyridoxine and curcumin, on kidney functional indices in diabetic nephropathy patients

Protocol summary

Study aim

Comparison the effect of advanced glycation end-products (AGEs) restricted diet and combined supplementation of zinc, pyridoxine and curcumin, on kidney functional indices in diabetic nephropathy patients

Design

Randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

Individuals referred to Motahhari Clinic in Shiraz, were evaluated by the kidney specialist (clinical partner of the project), if the initial inclusion criteria were confirmed, further evaluation were performed, then randomized to one of 3 study groups and received the desired intervention. The patients and the outcome assessor of the study were blind to the study group.

Participants/Inclusion and exclusion criteria

Study population: patients (male / female) with diabetes mellitus Inclusion criteria: Willingness to participate، diagnosis of diabetes by a specialist, diagnosis of nephropathy by a specialist (patient with a minimum GFR equal to or more than 30 ml per minute and microalbuminuria or macroalbuminuria stage), no alcohol and tobacco usage, stable weight during the last 6 months (self-report), constant type and dose of drugs used in the last 6 months (self-report) Exclusion criteria: Acute heart diseases, liver, gastrointestinal, thyroid and parathyroid, rheumatoid and infectious diseases, stroke, pregnancy and lactation, use of any dietary supplement in the last 6 months (self-report)

Intervention groups

Study duration: 10 weeks for all groups Control group: Diabetic diet (DD) plus 3 placebo capsules (non-absorbale starch); Intervention group 1: DD plus 3 placebo capsules plus dietary instructions to reduce the content of AGEs; Intervention group 2: DD plus 3 capsules (pyridoxine (100mg) plus zinc (30mg) plus curcumin (1g) - 1 after each main meal). Drugs and placebo are provided by Abu Reihan pharmacy company.

Main outcome variables

Estimated glomerular filtration rate, urinary microalbumin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191004044979N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **retrospective**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name
Arash Dashtabi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2019-11-22, 1398/09/01

Actual recruitment end date

2020-03-10, 1398/12/20

Trial completion date

2020-05-21, 1399/03/01

Scientific title

Comparison of the effect of advanced glycation end-products restricted diet and combined supplementation of zinc, pyridoxine and curcumin, on kidney functional indices in diabetic nephropathy patients

Public title

advanced glycation end-products on Diabetic Nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Diabetes diagnosis by a specialist physician (based on criteria of the American Diabetes Association) Diagnosis of nephropathy by a specialist physician (based on criteria of the American Diabetes Association), patient with a minimum GFR equal to or greater than 30 mL / min / 1.73 m2 and in microalbuminuria (299-30 mg / g Cr) or macroalbuminuria (mg / g Cr) 300≤) No use of alcohol and tobacco Constant weight during the last 6 months (self-report) The constancy of the type and dose of drugs in the past 6 months (self-report)

Exclusion criteria:

Occurrence of acute heart disease, stroke, liver or gastrointestinal diseases, thyroid and parathyroid disease, rheumatoid arthritis and infectious Pregnancy or lactation Using any dietary supplement in the past 6 months (self-report)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **93**

Actual sample size reached: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned to one of three groups according to the block-randomization protocol (produced by Random Allocation Software): 1-control 2-intervention (dietary) 3-intervention (pyrodoxin + zinc + curcumin supplement) in 1: 1: 1 fashion. Since allocation sequence is made by computer software and the output is only the list of assigned participant numbers, the research team will not interfere or know how individuals are assigned (randomization and concealment).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted in a double-blind manner for more accuracy, so that the researcher is aware of the type of interventions distributed among the study subjects, but the participants and outcome assessor are not aware of the type of intervention applied. Placebo capsules are same in size, color, and odor compared to the intervention capsules, and none of the participants will know which of the three groups they are classified into. Also, outcome assessor has no information about which group the participants were in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ethics Committee in Medical Sciences Research - Vice Chancellor for Research and Technology of Shiraz University of Medical Sciences - Seventh Floor - Central Building of Shiraz University of Medical Science - Zand St.

City

Shiraz

Province

Fars

Postal code

713451978

Approval date

2019-09-03, 1398/06/12

Ethics committee reference number

IR.SUMS.REC.1398.798

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08.2

ICD-10 code description

Diabetes mellitus due to underlying condition with kidney complications

2

Description of health condition studied
Diabetic nephropathy
ICD-10 code
E08.21
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic nephropathy

Primary outcomes

1

Description
Urine microalbumin
Timepoint
At start and after 10 weeks of intervention
Method of measurement
Biochemical (with special kits made by BIOREX company by immunoturbidometric method)

2

Description
Estimated glomerular filtration rate
Timepoint
Before intervention and 10 weeks after intervention
Method of measurement
The CKD-EPI Creatinine Equation for Glomerular Filtration Rate

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Diabetic diet based on approved guideline of american diabetes association (1500-1800 calorie, 55–65% carbohydrate, ≤30% fat, and 10–20% protein) plus 3 placebo capsules produced by Abu Reyhan company (after each meal- containing non-absorbable starch) for 10 weeks
Category
Placebo

2

Description
Intervention group: Diabetic diet based on approved guideline of american diabetes association (1500-1800 calorie, 55–65% carbohydrate, ≤30% fat, and 10–20% protein) plus 3 placebo capsules produced by Abu Reyhan company (after each meal - containing non-absorbable starch) plus instructions for reducing the amount of advanced glycation end-products compounds in foods based on prior studies for 10 weeks
Category
Treatment - Other

3

Description
Intervention group: Diabetic diet based on approved guideline of american diabetes association (1500-1800 calorie, 55–65% carbohydrate, ≤30% fat, and 10–20% protein) plus 3 capsules containing curcumin (produced by Abu Reyhan company), zinc (produced by Nature Made company) and pyridoxine (produced by Health Aid company), (Totally contains 1 gram of curcumin, 30 mg of zinc, 100 mg of pyridoxine- after each main meal) for 10 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Specialty Clinic, Shiraz University of Medical Sciences
Full name of responsible person
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Motahari Clinic, Namazi Square, Shiraz, Iran.
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Arash Dashtabi

Position
PhD Candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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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