

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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-absorbable 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3725 1005

##### Email address

arash.dashtabi@yahoo.com

##### 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 m<sup>2</sup> 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 (pyridoxin + 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,  $\leq$ 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,  $\leq$ 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,  $\leq$ 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

Arash Dashtabi

##### Street address

Motahari Clinic, Namazi Square, Shiraz, Iran.

##### City

Shiraz

##### Province

Fars

##### Postal code

71473771348

##### Phone

+98 71 3612 1000

##### Email

motahari@sums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shiraz Faghihi Clinic, Shiraz University of Medical Sciences

##### Full name of responsible person

Arash Dashtabi

##### Street address

Next to medical school, Karim Khan Zand Boulevard, Shiraz.

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##### Province

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##### Postal code

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##### Email

faghihihsp@sums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

**Street address**

Vice Chancellor for Research and Technology-  
Seventh Floor- Central Building of Shiraz University of  
Medical Sciences- Zand St.- Shiraz- Iran.

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**Province**

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+98 71 3235 7282

**Email**

vcrdep@sums.ac.ir

**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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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Full professor

**Latest degree**

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**Other areas of specialty/work**

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### Person responsible for updating data

**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

**Street address**

School of Nutrition and Food Sciences, Razi Blvd,  
Shiraz, IR Iran.

**City**

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**Province**

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**Email**

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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