Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Investigation of the effect of a combination of specific amino acids oral supplements in patients with diabetic nephropathy: a randomized controlled phase 1 clinical trial

Protocol summary

Study aim

In order to reduce the progression of nephropathy in diabetic patients, a clinical trial study has been designed to evaluate the effectiveness of oral supplementation resulting from the combination of 7 amino acids in diabetic nephropathy patients with a limited protein diet. In phase 1, the safety of the compound is evaluated.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 1 on 60 patients. block Randomization method is used for randomization.

Settings and conduct

60 eligible diabetic nephropathy patients are selected in the office of a nephrologist. Patients are prescribed a low-protein diet of 0.6 to 0.8 grams per kilogram per day. 30 patients will be considered as controls and will receive a placebo, and 30 patients will be treated with oral supplements. The double-blind method is used that both patients, physicians and evaluators of results are not aware of the supplementation group or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men or women over 18 years of age with type 1 or type II diabetes and kidney disease with a 30-300 mg urinary albumin level in 24 hours. Exclusion criteria: People with chronic inflammatory or autoimmune diseases, CKD due to reasons other than diabetes, organ transplants, blood pressure 16 to 9 and above, etc., and if patients do not follow a diet with limited protein.

Intervention groups

The oral supplement contains 1 g of glycine, 1 g of L -glutamic acid, 1 g of L -glutamine, 0.7 g of alanine, 0.5 g of lysine, 0.5 g of arginine plus 1 g of creatine. The contents are diluted in 50 ml of water and patients will consume it twice a day for 3 months. The starch powder will be used as a placebo.

Main outcome variables

Measurement of biochemical parameters to assess the safety of compound: creatinine, blood urea nitrogen, sodium and potassium and 24-hour urinary albumin

General information

Reason for update

Acronym

DN or DKD

IRCT registration information

IRCT registration number: **IRCT20210822052252N1**
Registration date: **2021-09-05, 1400/06/14**
Registration timing: **prospective**

Last update: **2021-09-05, 1400/06/14**
Update count: **0**

Registration date

2021-09-05, 1400/06/14

Registrant information

Name

Alieh Gholaminejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of a combination of specific amino acids oral supplements in patients with diabetic nephropathy: a randomized controlled phase 1 clinical trial

Public title

investigation of the effect of specific amino acids in diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years or older men or non-pregnant and non-lactating women with type 1 or type II diabetes and kidney disease Participants with albumin in urine: Diabetic patients whose albumin level is 30-300 mg / 24h is used for this study (stage 3 of the stages of diabetic nephropathy) Willingness and ability to consciously consent and cooperate with the protocol, including discontinuation of current hypertension medications if necessary

Exclusion criteria:

Pregnant or lactating women People with inflammatory or chronic autoimmune diseases People with chronic kidney disease for reasons other than diabetes People with organ transplants People with blood pressure 16 over 9 and above People with hepatitis B or C viral liver infection, liver cirrhosis or significant liver disease People with recent gastrointestinal bleeding People with acute kidney damage in the 3 months before screening Individuals who have undergone major surgery within 3 months prior to screening or plan to have it during the study period. People with HIV infection with the virus that causes AIDS. People with heart disease that is not considered stable. People with active cancer or another disease that greatly increases the risk of cancer. People with the need to take drugs that alter the immune system. The patient's do not follow a diet with limited protein.

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. In this two-group experiment, we will have blocks with 60 members (including 30 participants in the intervention group and 30 participants in the control group). Randomization tool is also Random allocation software that is able to generate random sequences by blocking method. We also use random allocation concealment with the central method so that the assigned group is not known before the individual is assigned. In this method, a random sequence is provided to a specific person or center, and the researcher, based on the order in which participants enter the study, communicates with the relevant center about the group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to reduce bias related to the intervention and evaluate the consequences, the double-blind method is followed. In this method, the trial is planned in such a way that the participant does not know which of the two control or test groups it belongs to, and the physician and the results evaluator (data analyzer) do not know what treatment is for which patient. Therefore, only the lead researcher is aware of the grouping of participants. One of the most common methods of blinding in RCTs is the use of seemingly identical drugs. In this study, we will use amino acid powder as a “active” drug and starch powder as a "placebo" and we will provide both in the same cans to the doctor and finally to the patients. It is impossible for patients and physicians to determine which drug and which placebo. To blind the results evaluator, we use the coding method in such a way that for each patient, regardless of the existing grouping, a code is assigned that is stored in the main file of information with the main researcher and patient information and data will be given to the evaluator with this code.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Isfahan university of medical sciences

Street address
Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-05-08, 1400/02/18
Ethics committee reference number
IR.MUI.MED.REC.1400.100

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
creatinine (GFR)
Timepoint
at the beginning of the trial, and after each month.
Method of measurement
Enzymatic calorimetric assay

2

Description
blood urea nitrogen
Timepoint
at the beginning of the trial, and after each month.
Method of measurement
Enzymatic method (urease)

3

Description
sodium and potassium in serum
Timepoint
at the beginning of the trial, and after each month.
Method of measurement
Electrolyte analyzer

4

Description
24-hour urinary albumin
Timepoint
at the beginning and end of the trial
Method of measurement
Bromocresol green. Colorimetric

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The oral supplement contains 1 g of glycine, 1 g of L -glutamic acid, 1 g of L -glutamine, 0.7 g of alanine, 0.5 g of lysine, 0.5 g of arginine plus 1 g of creatine. The contents are diluted in 50 ml of water (PH = 6.4) and patients will consume it twice a day for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Starch powder will be used as a placebo for patients in the control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital, office of a nephrologist
Full name of responsible person
Mrs. Dr. Mojgan Mortazavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Alieh Gholaminejad

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Biotechnology

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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