Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation of the effect of probiotic supplementation on the improvement of proteinuria in patients with immunoglobulin A nephropathy

Protocol summary

Study aim
Evaluation of the effect of probiotic supplementation on the improvement of proteinuria in patients with immunoglobulin A nephropathy

Design
This clinical trial was performed on 120 patients, divided into two groups of 60, including a control group and parallel groups. This study is Double-blind and block randomization method is used.

Settings and conduct
All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age over 18 years, Early IgA nephropathy diagnosed by biopsy, Albuminuria more than 0.75 grams per day, Serum creatinine less than 200 micromoles per liter, Creatinine clearance greater than 30 ml per minute Exclusion Criteria: Inflammatory diseases, Diabetes, Celiac, Cancer, AIDS, Autoimmune diseases, Pregnancy, Breastfeeding, Secondary IgA nephropathy, Allergy to probiotics

Intervention groups
Patients in the intervention group, in addition to standard treatment (omega 3 capsules 1000 mg and valsartan), receive probiotic capsules once a day for six months, and the control group also receive a placebo according to the above method.

Main outcome variables
Body Mass Index (BMI), 24-hour urinary protein level, Duration of illness, side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190415043279N11**
Registration date: **2022-03-07, 1400/12/16**
Registration timing: **prospective**

Last update: **2022-03-07, 1400/12/16**
Update count: **0**

Registration date
2022-03-07, 1400/12/16

Registrant information

Name
Pezhman Sharifi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-10-07, 1401/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of probiotic supplementation on the improvement of proteinuria in patients with immunoglobulin A nephropathy

Public title

Evaluation of the effect of probiotic supplementation on the proteinuria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Early IgA nephropathy diagnosed by biopsy Albuminuria more than 0.75 grams per day Serum creatinine less than 200 micromoles per liter Creatinine clearance greater than 30 ml per minute

Exclusion criteria:

Inflammatory diseases Diabetes Celiac Cancer AIDS Autoimmune diseases Pregnancy Breastfeeding Secondary IgA nephropathy Allergy to probiotics

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method with a block size of 4. Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive Probiotic Capsule and the other will receive placebo. The participants and administrator do not have any information about content of capsules (double blinded study). The list of randomization was computer-generated. supplements and placebo capsules were placed in completely identical packages and were coded by someone who was unaware of the nature of the study in numbered bottles based on the list. And another person who was unaware of the contents of the pack provided them to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2021-12-21, 1400/09/30

Ethics committee reference number

IR.MUK.REC.1400.255

Health conditions studied

1

Description of health condition studied

IgA nephropathy

ICD-10 code

E08.21

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic nephropathy

Primary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

by measuring height and weight using a scale and height meter

2

Description

24-hour urinary protein level

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

laboratory kit

3

Description
Duration of illness
Timepoint
Examination by a nephrologist once every two months until the end of the 6-month period (three times)
Method of measurement
Patient file

4

Description
side effects
Timepoint
Periodically every month until the end of 6 months
Method of measurement
Telephone contact with patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Omega 3 capsules 1000 mg and Valsartan in addition to probiotic capsules of Milad Pouya Company Probiotic Capsules, approved by the US Food and Drug Administration and under the brand name Prodigest, are taken once a day for six months.
Category
Placebo

2

Description
Control group: Omega 3 capsules 1000 mg, Valsartan plus placebo are taken as one capsule once a day for six months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology Clinic of Tohid Hospital
Full name of responsible person
Dr. Mohammad Saad Forghani
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sanandaj 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
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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