Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of probiotic consumption on acidosis in patients with chronic kidney failure (CKD) with end stage renal disease (ESRD) whom referred to Luqman Hakim Hospital from September 2023 to Mars 2024

Protocol summary

Study aim

Investigating the effect of probiotics on acidosis in patients with chronic kidney failure (CKD) who visited Luqman Hakim Hospital in the second half of 1402.

Design

The upcoming trial will be a phase 2, double-blind study involving 50 individuals with end-stage renal failure. The study population will be separated into intervention and control groups using the sealed envelope approach. The intervention group will be given prebiotic pills, while the control group will be given a placebo, and the arterial blood gases of all patients will be compared three months after the intervention to the baseline level.

Settings and conduct

The study location is Luqman Hakim Hospital. The study is a double-blind trial, which means that following randomization, each patient is assigned a label that only the study supervisor is aware of. Patients will be tested for arterial blood gases once before and once after receiving the medication or placebo for three months.

Participants/Inclusion and exclusion criteria

Inclusion: Age between 18 and 60 years, confirmed chronic renal failure for at least 3 months, and under the same dialysis machines and similar filters. ; Exclusion: history of kidney transplant, any possible cause other than CKD for creatinine drop, other causes of metabolic acidosis, use of metformin and antihypertensive drugs.

Intervention groups

The intervention group participants are requested to take the prebiotic tablets provided to them everyday after lunch for three months. Cap Lactocare 109 CFU (Cap Lactocare) is the medication utilized. The placebo tablets will be administered to the control group at the same dose.

Main outcome variables

The primary outcome of the study will be arterial blood gases and serum creatinine level and glomerular filtration rate will be the secondary outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230608058421N1**
Registration date: **2023-06-29, 1402/04/08**
Registration timing: **prospective**

Last update: **2023-06-29, 1402/04/08**
Update count: **0**

Registration date

2023-06-29, 1402/04/08

Registrant information

Name

Melika Gholizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9005

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melika_g1368@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotic consumption on acidosis in patients with chronic kidney failure (CKD) with end stage renal disease (ESRD) whom referred to Luqman Hakim Hospital from September 2023 to Mars 2024

Public title

The effect of probiotics on patients with end-stage renal failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age of entering the study is considered between 18 and 60 years. Confirmation of chronic kidney failure from the patient's tests or documents that show a structural or functional disorder, or in other words, albuminuria or creatinine drop. More than three months have passed since the mentioned disorders. Affected patients should be under the same dialysis machines and similar filters.

Exclusion criteria:

History of kidney transplant Any possible cause other than CKD for creatinine drop Other causes of metabolic acidosis such as diarrhea, heart failure or shock Metformin use Taking blood pressure lowering medications due to the possibility of acidosis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Researchers prepare identical envelopes, each containing a piece of paper indicating a treatment group. The envelopes are shuffled randomly, sealed, and sequentially assigned to participants as they enroll in the study. An independent person opens the envelope assigned to each participant, revealing their treatment group. This method ensures that the treatment assignment remains concealed until the moment of assignment, reducing the potential for bias or manipulation by researchers. It enhances the study's integrity and validity by promoting fairness in treatment allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

To achieve double blinding in this study, researchers ensure that both participants and investigators are unaware of the treatment assignments. This involves preparing treatments or interventions that look identical. Randomization is performed using a predetermined schedule, and each treatment is assigned a unique code known only to an independent coordinator. The treatments are labeled with these codes, masking their actual identities. Participants are then assigned treatments based on the randomization schedule, without revealing the true nature of the assigned treatment. Throughout the study, both participants and investigators remain blinded to the treatment allocations, reducing the potential for bias and ensuring the integrity of the research findings.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjac, Daneshju Blvd, Koodakyar Ave

City

Tehran

Province

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Postal code

1985717443

Approval date

2023-06-03, 1402/03/13

Ethics committee reference number

IR.SBMU.MSP.REC.1402.099

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description
arterial blood pH
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Arterial blood gas measurement will be assessed by the optical method by the Edan device in the laboratory of Luqman Hakim Hospital

2

Description
Arterial blood HCO3
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Arterial blood gas measurement will be assessed by the optical method by the Edan device in the laboratory of Luqman Hakim Hospital

Secondary outcomes

1

Description
Serum creatinine level
Timepoint
Before intervention and 3 months after intervention
Method of measurement
It will be assessed by the Pars Azmoon kit in the laboratory of Luqman Hakim Hospital

2

Description
glomerular filtration rate
Timepoint
Before intervention and 3 months after intervention
Method of measurement
eGFR (mL/min)= [(140 - age) × Wt / (0.814 × Serum Creatinine level in µmol/L)] × (0.85 if female)

Intervention groups

1

Description
Intervention group: Probiotic group, patients in this group will be advised to take probiotic capsules orally every day after lunch for three months. The medicine used will be Cap Lactocare 109 CFU (Cap Lactocare).
Category
Treatment - Drugs

2

Description
Control group: Intervention group: patients in this group will be advised to take placebo capsules orally every day after lunch for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Luqman e Hakim hospital
Full name of responsible person
Farzaneh Fotuhi
Street address
Sough Kargar Ave, Kamali Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ali Ziyaie
Street address
Velenjak, Daneshju Blvd, Kooakya Ave
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farzaneh Futuhi

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
nephrologist

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Position
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The study protocol, clinical analysis map, informed consent form, clinical study report, codes used in analysis and data dictionary will be published in an article that shows the final results of the work.

When the data will become available and for how long
The start of the access period immediately after the publication of the results of the article

To whom data/document is available
The data will be available to researchers and industry.

Under which criteria data/document could be used
The permission to perform the analysis will be given only for the purpose of performing meta-analysis in the field of systematic review studies.

From where data/document is obtainable
To receive the data, send a message to the responsible author of the study, Dr. Farzaneh Fatuhi. Access is possible only through email ff.1975@yahoo.com.

What processes are involved for a request to access data/document
Applicants should send the requested texts and the code of ethics of their desired research along with the work

resume to the mentioned email.

Comments