Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of probiotic supplementation on progression of Carotid intima-media thickness after kidney transplantation, a triple blinded clinical trial study

Protocol summary

Study aim
Determination of probiotic supplementation effect on early atherosclerosis after kidney transplantation

Design
A controlled clinical trial with parallel groups, triple-blind, randomized, on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct
A randomized, triple-blind clinical trial that will be conducted on transplant patients after transplantation. The intervention group will receive a probiotic supplement for three months and the control group will receive a placebo once a day for three months. Carotid intima-media thickness will be measured at the beginning and end of the study and compared in the two groups. The researcher, participants, and the analyst are blinded in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: First kidney transplant, at least three months after transplantation, no impairment of allograft function before study initiation Exclusion criteria: Multiple transplants, graft loss during the first trimester, hepatitis, smoking, diabetes, pregnancy, history of cardiovascular disease, graft rejection before and after study entry, malignancy, liver cirrhosis

Intervention groups
The intervention group will take one probiotic tablet daily for three months. The control group will also receive one placebo tablet daily for three months.

Main outcome variables
Intima media carotid thickness; serum interleukin 6; hs_CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250609066136N1**
Registration date: **2025-08-12, 1404/05/21**
Registration timing: **prospective**

Last update: **2025-08-12, 1404/05/21**
Update count: **0**

Registration date
2025-08-12, 1404/05/21

Registrant information

Name
Somaye-Sadat Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 23871

Email address
somayedadat_heidary@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2028-03-19, 1406/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of probiotic supplementation on progression of Carotid intima-media thickness after

kidney transplantation, a triple blinded clinical trial study

Public title
effect of probiotic supplementation in transplant patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
First kidney transplant at least three months after transplantation no impairment in allograft function prior to study entry
Exclusion criteria:
Multiple transplants graft loss during the first three months hepatitis smoking, diabetes pregnancy history of cardiovascular diseasث graft rejection before and after study malignancy liver cirrhosis
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The study population will be completely randomly divided into 2 groups three months after the transplant and when kidney function has stabilized based on the physician's diagnosis. Randomization will be performed using a stratified blocked randomization method based on gender and age as the blocks. Blocks will be considered as 4.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The study will be conducted in a triple-blind manner, so that the main investigator, the study population, and the results analyst will not be aware of the type of randomization in the groups and the type of intervention. The company producing the probiotic and placebo will send the product to the researcher in a coded form, and the researcher will not be aware of the coding until the end of the analysis. When the results are analyzed, the codes will be announced by the company and it will be clear what type of intervention each person received.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Urology and Nephrology Research center, Shahid Beheshti University of M
Street address
Shahid Beheshti University of Medical Sciences, Arabi St, Velenjak
City
Tehran
Province
Tehran
Postal code
4631- 19395
Approval date
2024-03-07, 1402/12/17
Ethics committee reference number
IR.SBMU.UNRC.REC.1402.019

Health conditions studied

1

Description of health condition studied
kidney transplant
ICD-10 code
Z94.0
ICD-10 code description
Kidney transplant status

2

Description of health condition studied
Atherosclerosis
ICD-10 code
I65.2
ICD-10 code description
Occlusion and stenosis of carotid artery

Primary outcomes

1

Description
Intima- media carotid thickness
Timepoint
before and 3 months after intervention initiation
Method of measurement
Doppler sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Will receive one probiotic supplement daily produced by Zist Tahmir Company. This supplement contains the following bacterial strains: Lactobacillus rhamnosus Lactobacillus plantarum Lactobacillus casei Lactobacillus helveticus Lactobacillus acidophilus Lactobacillus bulgaricus 109CFU Blend Lactobacillus gasseri Bifidobacterium bifidum Bifidobacterium lactis Bifidobacterium breve Bifidobacterium longum Streptococcus thermophile .Carotid intima-media thickness will be measured before the intervention and at the end of three months of probiotic consumption using Doppler ultrasound. Participants will be excluded from the study if they do not tolerate the probiotic.

Category
Other

2

Description
Control group: will receive one placebo produced by Zist Takhimr Company daily. Carotid intima-media thickness will be measured before the intervention and at the end of three months of probiotic consumption using Doppler ultrasound. Participants will be excluded from the study if they do not tolerate the probiotic.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Labbafi-Nejad Hospital

Full name of responsible person
Somaye-Sadat Heidari

Street address
No 103,, 9th Boostan, Pasdaran

City
Tehran

Province
Tehran

Postal code
1666668111

Phone
+98 21 2259 4197

Email
somayesadat_heidary@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mostafa Rezaei Tavirani

Street address
., Shahid Beheshti University of Medical Sciences, Arabi St, Daneshjoo Blvd, Velanjak

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
urm@sbmu.ac.ir

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
Somaye-Sadat Heidari

Position
Health researcher

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
Research Institute for Urology and Nephrology, No. 103, 9th Boostan St, Pasdaran St

City
Tehran

Province
Tehran

Postal code
1666668111

Phone
+98 21 2259 4197

Email
somayesadat_heidary@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Somaye_Sadat Heidari

Position
health researcher

Latest degree
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Other areas of specialty/work
Biochemistry

Street address
Research Institute for Urology and Nephrology, No. 103, 9th Boostan St, Pasdaran St

City
Tehran

Province
Tehran

Postal code
1666668111

Phone
+98 21 2256 4197

Email
somayesadat_heidary@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Somaye-Sadat Heidari

Position
health researcher

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Research Institute for Urology and Nephrology, No 103, 9th Boostan, Pasdaran Ave

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Tehran

Province
Tehran

Postal code
1666668111

Phone
+98 21 2259 4197

Email
somayesadat_heidary@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Information related to the main outcome can be shared.

When the data will become available and for how long
Access period starts one month after the result publication.

To whom data/document is available
people working in academic institutions

Under which criteria data/document could be used
Data integration with other sources is only permitted with the approval of the ethics committee. Only analyses that do not result in re-identification of individuals are permitted.

From where data/document is obtainable
Vice-Chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences, Velenjak, Arabi St., Tehran, Postal Code 4631-19395

What processes are involved for a request to access data/document
Request to Vice President for Research and Technology, Shahid Beheshti University of Medical Sciences

Comments