

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Aug 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 diseases 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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	kidney transplant
ICD-10 code	Z94.0
ICD-10 code description	Kidney transplant status
<u>2</u>	
Description of health condition studied	Atherosclerosis
ICD-10 code	I65.2
ICD-10 code description	Occlusion and stenosis of carotid artery
Primary outcomes	
<u>1</u>	
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

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1666668111

Phone

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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

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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

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

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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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