

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of probiotics on the serum level of endotoxin, the faecal levels of endotoxin and DNA damage in peripheral blood mononuclear lymphocytes of dialysis patients

Protocol summary

Study aim

This study aims to investigate the effects of taking probiotics on the level of bacterial endotoxin in serum as the index of intestinal immune, the level of endotoxin in faeces sample and DNA damage of peripheral blood mononuclear lymphocytes in dialysis patients.

Design

A controlled, permuted block randomization clinical trial in 41 dialysis patients for 6 months.

Settings and conduct

This study will be conducted on the dialysis ward of Imam Hossein hospital. The patients who will sign informed consent will be divided into two groups. Demographic information will be collected using a demographic questionnaire through intervention and then five cc blood sample and faecal sample will be taken. The intervention will be begun by giving probiotics capsules to the participants for 6 months. At the end of the intervention, blood and faecal samples will be taken again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: over 18 years of age, glomerular filtration rate less than 15 ml/min, having routine diets
Exclusion Criteria: infectious diseases, pregnancy (for female participants), autoimmune or immunosuppressive diseases, treatment with immunosuppressive drugs or antibiotics, lactose intolerance

Intervention groups

The intervention group: taking a probiotics capsule daily
The control group: taking no intervention

Main outcome variables

Serum endotoxin level, faecal endotoxin level, DNA damage in peripheral blood mononuclear lymphocytes

General information

Reason for update

to complete the information of the study

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103130603N1**

Registration date: **2017-04-14, 1396/01/25**

Registration timing: **prospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **1**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

Alireza Jafar

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

alireza.jafar@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics on the serum level of endotoxin, the faecal levels of endotoxin and DNA damage in peripheral blood mononuclear lymphocytes of dialysis patients

Public title

The effect of probiotics on infectious disease and DNA damage in lymphocytes of dialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

over 18 years of age, glomerular filtration rate less than 15 ml/min, having routine diets

Exclusion criteria:

infectious diseases, pregnancy (for female participants), autoimmune or immunosuppressive diseases, taking immunosuppressive drugs or antibiotics, lactose intolerance

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization assignment will be done based on sample size and permuted blocked method into four groups using computer-generated random numbers and written on closed envelopes. The participants who will sign informed consent will be divided into control or intervention groups. The allocation will be concealed from participants by closed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical

Sciences

Street address

Haft-e-Tir Square, Shahroud, Iran

City

Shahroud

Province

Semnan

Postal code

3613773955

Approval date

2016-10-08, 1395/07/17

Ethics committee reference number

ir.shmu.rec.1395.113

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Serum level of endotoxin

Timepoint

Before and after the intervention (6 months)

Method of measurement

Limulus Amebocyte Lysate (LAL) kit

2

Description

DNA Damage of peripheral blood mononuclear lymphocytes

Timepoint

Before and after the intervention (6 months)

Method of measurement

Comet Assay

3

Description

faecal level of endotoxin

Timepoint

Before and after the intervention (6 months)

Method of measurement

Limulus Amebocyte Lysate (LAL) kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: taking probiotics capsule (4BioCap 180 mg) made by Tehran Daroo company Containing: Lactobacillus acidophilus, Bifidobacterium SPP, Streptococcus thermophilus, Lactobacillus delbrueckii bulgaricus, Dosage & Duration: 6 months, 1 capsule per day

Category

Treatment - Drugs

2

Description

Control group: taking no intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital of Shahroud

Full name of responsible person

Alireza Jafar

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Imam Hossein Square, Shahroud, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hossein Emamian

Street address

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emamian@shmu.ac.ir

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Alireza Jafar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mehdi Mirzaii

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Bacteriology
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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

Undecided - It is not yet known if there will be 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

Serum level of endotoxin, faecal level of endotoxin and DNA damage of peripheral blood mononuclear lymphocytes

When the data will become available and for how long

After publishing the related article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Without any condition

From where data/document is obtainable

Vice-Chancellor for Research, Shahroud University of Medical Sciences

What processes are involved for a request to access data/document

By sending a request email

Comments