Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
faecel level of endotoixn

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
Street address
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
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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
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
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Other areas of specialty/work
General Practitioner
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Associate professor
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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