Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Lactobacillus Rhamnosus and Inulin supplements (singly & both) on phenolic uremic toxins, nutritional status and FGIDs in hemodialysis patients

Protocol summary

Summary

Objectives: Effects of Lactobacillus Rhamnosus and Inulin supplements (singly & both) on phenolic uremic toxins; nutritional status and FGIDs in hemodialysis patients. Design: Double blind randomized clinical trial. Setting and conduct: 96 eligible ESRD treated by hemodilysis which meet the inclusion criteria during will be selected and blocked randomly divided into 3 intervention group: a)Probiotic Lactobacillus Rhamnosus b)Prebiotic Inulin c)Symbiotic Lactobacillus Rhamnosus and Inulin; Control group: Placebo. Intervention: Target group receives 16 billion CFU probiotic Lactobacillus Rhamnosus per day as one capsule after meal for 28 days (prepared by Nutrition Research Center from yogurt and cheese of different farms located in the suburbs Heris), and receives 10 grams per day prebiotic Inulin as one sachet after meal for 28 days, soluble dietary and ferment-able fiber, (prepared by BENEO Belgium from Cichorium intybus). Control group receives 10 g per day corn starch as one placebo sachet and one placebo capsule per day infant formula after meal for 28 days. Major Inclusion criteria: Both male and female; aged 20 years and older; acceptable performance of the digestive system; ability to drink at least 200 ml of water per day; life expectancy and survival at least 3 months; absence of acute medical conditions; accept and sign the project. Major Exclusion criteria: Patient reluctance to participate in the study; treated by peritoneal dialysis or kidney transplantation; intolerance supplements; pregnant women; lactating women; smoking; acute medical illness; use of antibiotics; psychedelic drugs; herbal medicines or flavors. Main primary outcome measures: The effect of supplements on serum levels of Uremic toxins (Paracresol and Phenol); nutrition status; energy intake; macronutrient intake; anthropometric measurements (weight, BMI), and FGIDs. Secondary outcome measures: The effect of supplements on intestinal and fecal microbiome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504182017N21**
Registration date: **2015-05-23, 1394/03/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-23, 1394/03/02

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences, Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Lactobacillus Rhamnosus and Inulin supplements (singly & both) on phenolic uremic toxins, nutritional status and FGIDs in hemodialysis patients

Public title

Effects of Lactobacillus Rhamnosus and Inulin supplements (singly & both) on phenolic uremic toxins, nutritional status and Functional GI Disorders (FGIDs) in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Physician definitive diagnosis of end stage of renal disease (ESRD) treated by hemodialysis; both male and female; aged 20 years and older; acceptable performance of the digestive system; ability to drink at least 100 ml of water per day; life expectancy and survival at least 3 months; absence of acute medical conditions; accept and sign the project. Exclusion criteria: Patient reluctance to participate in the study; treated with peritoneal dialysis or kidney transplantation; intolerance supplements; pregnant women; lactating women; smoking; acute medical illness; use of antibiotics; use of psychedelic drugs; use of herbal medicines and flavors.

Age

From **19 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neishaboori Avenue, Golgasht Street, Tabriz

City

Tabriz

Postal code

Approval date

2015-03-09, 1393/12/18

Ethics committee reference number

93197

Health conditions studied

1

Description of health condition studied

End stage kidney disease on dialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Serum levels of Phenol

Timepoint

Before and after intervention

Method of measurement

By HPLC method

2

Description

Serum levels of Paracresol

Timepoint

Before and after intervention

Method of measurement

By HPLC method

3

Description

Anthropometric measurements, Weight

Timepoint

Before and after intervention

Method of measurement

Weight using calibrated Seca scale with a precision of 0.1 kg

4

Description

Energy intake

Timepoint

Before and after intervention

Method of measurement

3 days food recall was used and analyzed with Nutritionist 4 software

5

Description

FGIDs, Symptoms in the Esophagus

Timepoint

Before and after intervention

Method of measurement

Using 93 items questionnaire based on ROM III

6

Description

FGIDs, Symptoms in the Stomach & Intestines

Timepoint

Before and after intervention

Method of measurement

Using 93 items questionnaire based on ROM III

7

Description

Anthropometric measurements, Body Mass Index

Timepoint

Before and after intervention

Method of measurement

Calculate: Weight divided to Square of Height

8

Description

Macronutrient intake, Proteins

Timepoint

Before and after intervention

Method of measurement

3 days food recall was used and analyzed with Nutritionist 4 software

9

Description

Macronutrient intake, Fats

Timepoint

Before and after intervention

Method of measurement

3 days food recall was used and analyzed with Nutritionist 4 software

10

Description

Macronutrient intake, Carbohydrates

Timepoint

Before and after intervention

Method of measurement

3 days food recall was used and analyzed with Nutritionist 4 software

11

Description

FGIDs, Symptoms in the Gall Bladder & Pancreas

Timepoint

Before and after intervention

Method of measurement

Using 93 items questionnaire based on ROM III

12

Description

FGIDs, Symptoms in the Rectum & Anal canal

Timepoint

Before and after intervention

Method of measurement

Using 93 items questionnaire based on ROM III

Secondary outcomes

1

Description

Intestinal (Stool) Microbiome, Bacteroidetes

Timepoint

Before and After Intervention

Method of measurement

Real-time PCR of DNA extracted from stool sample

2

Description

Intestinal (Stool) Microbiome, Firmicotes

Timepoint

Before and After Intervention

Method of measurement

Real-time PCR of DNA extracted from stool sample

Intervention groups

1

Description

Intervention group: Probiotic; Lactobacillus Rhamnosus (16 Billion CFU) one capsule per day for 28 days, after meal, prepared by Nutrition Research Center from yogurt and cheese of different farms located in the suburbs Heris.

Category

Treatment - Other

2

Description

Intervention group: Prebiotic; Inulin (10 grams) one sachet per day for 28 days, after meal, soluble dietary and ferment-able fiber, prepared by BENEO Belgium from Cichorium intybus.

Category

Treatment - Other

3

Description
Intervention group: Symbiotic; Lactobacillus Rhamnosus (16 Billion CFU, one capsule) with Inulin (10 grams, one sachet) per day for 28 days, after meal.
Category
Treatment - Other

4

Description
Control group: Corn starch (10 grams, one sachet) with Infant formula (one capusule) per day, for 28 days after meal, (Placebo)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Labbafinejhad Hospital
Full name of responsible person
Fatemeh Pourrezagholi
Street address
9th Boostan Avenue, Pasdaran Street, Tehran
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2

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Alireza Ostadrahimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
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Tabriz University of Medical Sciences, Attar Neishaboori Avenue, Golgasht Street
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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
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti university of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
ShahidBeheshti Universityof Medical Sciences, Velenjak Street, Shahid Chamran High Way, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Beheshti university of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty