

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Gastro-Resistant Capsules of synbiotic Reduced blood uremic toxins in hemodialysis patients: double-blind placebo-controlled randomized clinical trial.

Protocol summary

Study aim

Effects of synbiotic treatment on Uremic index in End stage renal disease

Design

In this research, 46 eligible patients referring to nor and aliasghar hospital chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

place: nor and aliasghar hospital blind: researcher and patient

Participants/Inclusion and exclusion criteria

Inclusion criteria performing hemodialysis treatment 3-times per week for at least 4 hours each time; not being pregnant or lactating; no history of active cancers (except for skin cancer); no history of severe chronic conditions such as pulmonary, cardiovascular, and hepatic diseases; no history of gastrointestinal disorders, HIV disease, and psychiatric problems. Exclusion criteria addiction to alcohol or drugs abuse; with severe edema; suffering from infections during 4 past weeks; those who used symbiotic, probiotic, prebiotic or antibiotics during 4 weeks preceding the study; those who used immune suppressive medicines, and anticoagulant agents were excluded

Intervention groups

synbiotic(Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium bereve, Bifidobacterium longum, Streptococcus thermophilus) and placebo

Main outcome variables

product uremic toxin in hemodialysis patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160528028120N1**

Registration date: **2018-01-19, 1396/10/29**

Registration timing: **retrospective**

Last update: **2018-01-19, 1396/10/29**

Update count: **0**

Registration date

2018-01-19, 1396/10/29

Registrant information

Name

soheila mirzaeian

Name of organization / entity

university

Country

Iran (Islamic Republic of)

Phone

+98 913 233 6801

Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2016-06-01, 1395/03/12

Expected recruitment end date

2016-12-01, 1395/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Gastro-Resistant Capsules of synbiotic Reduced blood uremic toxins in hemodialysis patients: double-blind placebo-controlled randomized clinical trial.

Public title

Symbiotic and blood uremic toxins in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

performing hemodialysis treatment 3-times per week for at least 4 hours each time, not being pregnant or lactating no history of active cancers (except for skin cancer) no history of severe chronic conditions such as pulmonary, cardiovascular, and hepatic diseases lack of gastrointestinal disorders, HIV disease, and psychiatric problems

Exclusion criteria:

those who used symbiotic, probiotic, prebiotic or antibiotics during 4 weeks preceding the study those who used immune suppressive medicines, and anticoagulant agents with severe edema addiction to alcohol or drugs abuse did not respond to the questions honestly and reported any side effects due to synbiotic consumption

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

Dual block Subjects will randomly allocated to block 1 and block 2 with the use of stratified block randomization according to gender, age (± 5 years) and hemodialysis duration (± 6 months).

Blinding (investigator's opinion)

Double blinded

Blinding description

double-blind To conduct the study in a double-blinded nature, the placebo and synbiotic capsules will encode as A and B, respectively, by a third person and patients and investigators will blind about the arms of the study

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University Of Medical Sciences

Street address

International Bureau, Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran, 81746 73461

City

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Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2015-11-15, 1394/08/24

Ethics committee reference number

194053

Health conditions studied

1

Description of health condition studied

end stage renal disease

ICD-10 code

I95.3

ICD-10 code description

Hypotension of hemodialysis

Primary outcomes

1

Description

indoxyl sulfate

Timepoint

1 and 8 weeks of treatment

Method of measurement

Eliza kit

2

Description

crp

Timepoint

1 and 8 weeks of treatment

Method of measurement

Eliza kit

Secondary outcomes

1

Description

phenol

Timepoint

1 and 8 weeks of treatment
Method of measurement
hplc

Intervention groups

1

Description

synbiotic The synbiotic capsules (GeriLact brand; ZIST TAKHMIR Company, Tehran; Iran) contained Lactobacillus casei (3.5×10⁹CFU), Lactobacillus acidophilus (1.5×10⁹CFU), Lactobacillus rhamnosus (3×10⁹CFU), Lactobacillus bulgaricus (3.5×10⁸CFU), Bifidobacterium breve (5×10⁹CFU), Bifidobacterium longum (1×10¹⁰CFU), Streptococcus thermophiles (3.5×10⁸CFU) as probiotic and fructooligosaccharide as prebiotic as well as lactose, magnesium stearate and talc as filling materials. During the 8-week intervention, the synbiotic group will receive 2 synbiotic capsules daily, between the main meals (500 mg per one capsule; one capsule per time), containing 1000mg synbiotic

Category

Treatment - Drugs

2

Description

placebo maltodextrin (2 capsules per day; 1000mg).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan's Noor and Saint Aliasghar Hospital's dialysis

Full name of responsible person

Mohammad Hassan Entezari

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Hezar-Jerib Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan university of medical sciences; research assistant part

Full name of responsible person

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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

Isfahan university of medical sciences; research assistant part

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

2

Sponsor

Name of organization / entity

Food Safety Research Center

Full name of responsible person

Mohammadhassan Entezari

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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

Food Safety Research Center

Proportion provided by this source

1

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

School of Nutrition and Food Sciences, Isfahan
University of Medical Sciences

Full name of responsible person

Soheila Mirzaeian

Position

phd student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

Nutrition

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۷۳۴۶۱-۸۱۷۴۶

Phone

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

all data except personal data

When the data will become available and for how long

2 year after publication

To whom data/document is available

academic researcher

Under which criteria data/document could be used

honest

From where data/document is obtainable

soheila.mirzaeian@yahoo.com

What processes are involved for a request to access

data/document

one week after request

Comments