

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

Effect of synbiotics supplement on fatigue and sleep quality in hemodialysis patients with chronic kidney disease

Protocol summary

Study aim

Determining the effect of synbiotic supplementation on fatigue and sleep quality in hemodialysis patients.

Design

Clinical trial with control group with parallel, double-blind, randomized, phase 3 groups on 60 patients. For randomization, 15 blocks of 4 permutations were used.

Settings and conduct

Among the patients referred to the dialysis ward of Musa Bin Jafar Hospital in Quchan, 60 patients will be selected based on inclusion and exclusion criteria. Participants and staff of the dialysis and data analysis department are unaware of the allocation of study groups. Supplemental capsules and placebo are similar in shape and size. At the beginning of the study, after obtaining written consent from all individuals, patients are randomly assigned to one of two groups receiving a synbiotic supplement or placebo. Patients should take the capsules twice daily with lunch and dinner during the 8 weeks of the intervention. Week 4 and the end of the study will be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 65 years, a patient with a diagnosis of chronic renal failure who has been on hemodialysis for at least 3 months. Exclusion criteria: Active infection during the last 30 days, use of antibiotics, prebiotics, probiotics, synbiotics, vitamin supplements or antioxidants during the last 30 days.

Intervention groups

Intervention group: Synbiotic lactoker 500 mg diet supplement (manufactured by Iran Bio Fermentation Company) contains high amounts of 12 beneficial bacterial strains along with fructooligosaccharide as a pre-biotic. Control group: Capsules containing corn starch with a synbiotic-like appearance.

Main outcome variables

Fatigue and sleep quality of patients with chronic kidney disease treated with hemodialysis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210117050055N1**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

Mina Jangpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8302

Email address

jangpoorm@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of synbiotics supplement on fatigue and sleep quality in hemodialysis patients with chronic kidney disease	
Public title	Effect of synbiotics supplement on fatigue and sleep quality in hemodialysis patients with chronic kidney disease
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: A patient with a diagnosis of chronic kidney disease who undergoing hemodialysis for at least 3 months. signing informed consent for participation in the study Patient with arteriovenous fistula or permanent catheter or venous arterial graft The patient undergoing hemodialysis 3 times a week for 4 hours each time Patient with KT / V> 1 Do not suffer from hearing and vision disorders No neurological disorders and a history of hospitalization in the psychiatric ward age range of 18 to 65 years Exclusion criteria: Active infection during the last 30 days Pregnant or lactating mothers Taking antibiotics, prebiotics, probiotics, synbiotics, vitamin supplements or antioxidants during the last 30 days Suffering from autoimmune diseases or connective tissue disorders History of cardiovascular diseases Diabetic foot infection Gastrointestinal diseases (inflammatory bowel disease, ulcerative colitis, Crohn's disease, celiac disease, lactose intolerance or allergy, irritable bowel syndrome) Liver disease (such as hepatitis B, hepatitis C) suffering from various types of malignancies Smoking more than 10 cigarettes per day Participate in other drug interventions hemoglobin less than 8 mg/dl PSQI score less than 6 (good sleep quality) acquisition of CFS score less than 18
Age	From 18 years old to 65 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	The randomization method in this study is based on quadratic blocks. Thus, fifteen blocks of four are formed and inside each block, two people are considered as intervention and two people as control. They will be in the control (receiving placebo) and intervention (receiving synbiotic supplement) groups.
Blinding (investigator's opinion)	Double blinded
Blinding description	Participants and staff in the dialysis and data analysis
	department are unaware of the allocation of study groups.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics Committee of Sabzevar University of Medical Sciences Street address No. 31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar City sabzevar Province Razavi Khorasan Postal code 9617913112- 31 صندوق Approval date 2021-01-13, 1399/10/24 Ethics committee reference number IR.MEDSAB.REC.1399.163
Health conditions studied	1 Description of health condition studied chronic kidney disease ICD-10 code N18.4 ICD-10 code description Chronic kidney disease, stage 4 (severe)
Primary outcomes	1 Description fatigue Timepoint 2 months Method of measurement Chalders Fatigue Scale 2 Description Sleep quality Timepoint

2 months

Method of measurement

Pittsburgh Sleep Quality Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention: Recipient of Lactococare synbiotic dietary supplement capsule (500 mg) containing 12 beneficial bacterial(Lactobacillus rhamnosus, Lactobacillus holotocus, Lactobacillus casei, Bifidobacterium lactis, Lactobacillus acidophilus, Bifidobacterium brochus, Lactobacillus bulgaricus, Bifidobacterium langobacum, Lactobacillus, Lactobacillus) strains with fructooligosaccharide as prebiotic (Made by Zist Tahkmir Iran Company)

Category

Treatment - Other

2

Description

Control group: Control group: receiving placebo capsules containing corn starch (500 mg) with a similar appearance to synbiotic capsules (Made by Zist Tahkmir Iran Company)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis ward of Musabne Jafar Hospital in Quchan city under the supervision of Mashhad University

Full name of responsible person

Shadi Pur Abbas

Street address

Imam Khomeini Ave

City

Quchan

Province

Razavi Khorasan

Postal code

1234567891

Phone

+98 58 3241 2995

Email

Shahriarssh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Qarat

Street address

No. 31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

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Web page address

<https://www.medsab.ac.ir/index.aspx?fkeyid=&siteid=1&fkeyid=&siteid=1&pageid=8659>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mina Jangpoor

Position

Master student of critical care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information on fatigue and sleep quality will be published in connection with the use of synbiotic supplements

When the data will become available and for how long

one year after the publication date

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Do not use the submitted data to print articles.

From where data/document is obtainable

Dr. Ali Asghar Jasmi. Email jesmiaa@gmail.com
Phone: 5144018300 پس از

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

The request will be submitted to the supervisor Dr. Ali Asghar Jasmi and his approval and registration in the Secretariat of Documents or Files.

Comments