

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of Synbiotics and Probiotics supplementation on renal function, systemic and vascular inflammations, heat shock protein 70 Antibody (HSP70) and cytokeratin-18 (k-18) in hemodialysis patients

Protocol summary

Summary

Objectives: The aim of this study is to investigate the effect of synbiotics (composition of Bifidobacterium and Lactobacillus and complex fiber), probiotic (Bifidobacterium and Lactobacillus) and placebo supplementation on renal function (GFR), systemic (hs-CRP, IL-6) and vascular (ICAM-1 and VCAM-1) inflammations, endotoxin, HSP 70 antibody and cytokeratin 18 (k-18) in hemodialysis patients design: In this double-blind randomized controlled trial, 75 male and female hemodialysis patients aged 65-30 years old, who are eligible for inclusion in the study will be recruited from hemodialysis ward of Ahwaz Imam Khomeini hospital. After obtaining Informed consent form all participants at the beginning of the study, Participants randomly allocated in three groups, receiving daily supplementation of synbiotics, probiotics or placebo for 8 weeks. Before starting dialysis, Blood and stool samples will be collected at the beginning and end of study. All anthropometric and physical activity variables will be measured both before and after the trial. To assess the dietary factors, the total amount of energy, macronutrients and micronutrients intake will be determined at the beginning and the end of the study. For this purpose 3-days 24-hour dietary recall will be completed by the patients and will be evaluated. Finally data will be analyzed by N4 software. Diets and medications dosage will be held constant throughout the study and each subject's exercise level will be kept constant and monitored by physical activity questionnaires (IPAQ).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041233393N1**

Registration date: **2017-04-23, 1396/02/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name

Neda Haghighat

Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 917 705 0021

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahwaz Jundishapour University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Synbiotics and Probiotics supplementation

on renal function, systemic and vascular inflammations, heat shock protein 70 Antibody (HSP70) and cytokeratin-18 (k-18) in hemodialysis patients

Public title

The effect of Synbiotics and Probiotics supplementation in reducing cardiovascular complications in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were: willingness to cooperate; at least 3 months renal failure on hemodialysis, 4 hours hemodialysis three times a week; aged between 65-30 years Exclusion criteria: history of kidney transplantation; infection; history of hospitalization in the last month; using any products or supplements containing probiotics and prebiotics and antibiotics in 1 months; using vitamins fiber omega-3 antioxidants within 3 weeks before or during the study; using nonsteroidal anti-inflammatory drug NSAIDs; progesterone, immunosuppressive drugs; diuretics and corticosteroids; the radiation in the area of small and large bowel; with Being irritable bowel syndrome; Crohn's disease or ulcerative colitis; a severe malnutrition (SGA: C); swelling and bloating

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,

Ethics Committee

City

Ahvaz

Postal code

15794-61357

Approval date

2017-02-25, 1395/12/07

Ethics committee reference number

IR.AJUMF.REC.1395.812

Health conditions studied

1

Description of health condition studied

hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

Antibody HSP70

Timepoint

at first and two months after intervention

Method of measurement

ELISA

2

Description

Interleukin -6

Timepoint

at first and two months after intervention

Method of measurement

ELISA

3

Description

ICAM-1

Timepoint

at first and two months after intervention

Method of measurement

ELISA

4

Description

VCAM-1

Timepoint

at first and two months after intervention

Method of measurement

ELISA

5

Description

Cytokeratin-18

Timepoint

at first and two months after intervention

Method of measurement

ELISA

6

Description

Endotoxin

Timepoint

at first and two months after intervention

Method of measurement

ELISA

7

Description

BUN

Timepoint

at first and two months after intervention

Method of measurement

Enzymatic

8

Description

keratinin

Timepoint

at first and two months after intervention

Method of measurement

Enzymatic

9

Description

hs-CRP

Timepoint

at first and two months after intervention

Method of measurement

ELISA

10

Description

The number of Lactobacillus colonies

Timepoint

at first and two months after intervention

Method of measurement

dilution

11

Description

The number of bifidobacter colonies

Timepoint

at first and two months after intervention

Method of measurement

dilution

Secondary outcomes

empty

Intervention groups

1

Description

Probiotics supplementation with one 5 gr Probiotics sachets (105 bifidobacter and lactobacilus) and two 5 gr saché of maltodextrin

Category

Prevention

2

Description

Synbiotics supplementation with two 5 gr saché of prebiotics (FOS, GOS, Inulin) and one 5 gr saché of probiotics (105 lactobacillus, bifidobacter)

Category

Prevention

3

Description

Placebo containing three 5 gr sachets of maltodextrin

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

hemodialysis center

Full name of responsible person

Dr Shaianfar

Street address

Emam khomeini hospital

City

ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr Makhmalzade

Street address

Vice chancellor for research, Ahvaz Jundishapour University of Medical Science, Ahvaz, Khuzestan

City

Ahvaz

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, Ahvaz Jundishapour
University of Medical Sciences

Proportion provided by this source

100

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

Contact

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Neda Haghighat

Position

Ph.D Candidate of Nutrition Science

Other areas of specialty/work

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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