

# 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)

###### Phone

+98 917 705 0021

###### Email address

haghighat.n@ajums.ac.ir

##### 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 sachés 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**

**Street address**

Dept of Nutrition, School of Paramedical, Ahvaz  
Jundishapur University of Medical Science, Ahvaz,  
Khouzestan

**City**

Ahvaz

**Postal code**

**Phone**

+98 61 3373 8330

**Fax**

**Email**

haghighat.n@ajums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Majid Mohammad Shahi

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Dept of Nutrition, School of Paramedical, Ahvaz  
Jundishapur University of Medical Science, Golestan  
Ave, Ahvaz, Khouzestan

**City**

Ahvaz

**Postal code**

**Phone**

+98 61 3373 8330

**Fax**

**Email**

shahi334@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz Jundishapour University of Medical Sciences

**Full name of responsible person**

Neda Haghighat

**Position**

Phd Candidate of Nutrition Science

**Other areas of specialty/work**

**Street address**

Dept of Nutrition, School of Paramedical, Ahvaz  
Jundishapur University of Medical Science

**City**

Ahvaz

**Postal code**

**Phone**

+98 61 3373 8330

**Fax**

**Email**

haghighat.n@ajums.ac.ir

**Web page address**

## 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*