

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the Efficacy of Probiotic Supplementation on bio-markers of inflammation and oxidative stress in pediatric patients under treatment with hemodialysis: randomized double blind clinical trial

#### Protocol summary

##### Study aim

Study of the Effect of probiotic in pediatric patients under hemodialysis treatment

##### Design

Clinical trial with control group in patients under hemodialysis with parallel group in double-blind design and randomized

##### Settings and conduct

This clinical trial performed in hemodialysis pediatric patients in Doctor Sheikh hospital in a randomized double blind design

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Hemodialysis Patients during study period Two week after Discontinue antibiotics Two weeks after resolving acute inflammatory settings Two weeks after Discontinue probiotics Exclusion Criteria Patients with Chronic Inflammatory Setting like glumerolonephritis or nephrotic syndrome Patients received antibiotic or under inflammatory setting like polmonary infection or gastroenteritis Candidate for transplantation Receiving immuno-suppressive drugs specially steroids Receiving probiotics for any reason

##### Intervention groups

Intervention group receive probiotics Probiotic contain following strains : Lactobacillus casei ,Lactobacillus acidophilus , Lactobacillus rhamnosus , Lactobacillus bulgaricus. Bifidobacterium breve , Bifidobacterium longum , Streptococcus thermophilus in the count of 10<sup>9</sup> CFU in 500 mg tablet from Zist Takhmir. Because these Bactria remain in the intestine and not absorb, nothing uptake during dialysis Control group receive placebo

##### Main outcome variables

Total Antioxidant Capacity; Nuclear factor-kappa B, vascular cell adhesion molecule,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160206026390N11**

Registration date: **2019-06-10, 1398/03/20**

Registration timing: **retrospective**

Last update: **2019-06-10, 1398/03/20**

Update count: **0**

##### Registration date

2019-06-10, 1398/03/20

##### Registrant information

##### Name

Ehsan Ghaedi

##### Name of organization / entity

Ahwaz Jundishapoor ,University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3285

##### Email address

ghaedi.e@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of the Efficacy of Probiotic Supplementation on bio-markers of inflammation and oxidative stress in pediatric patients under treatment with hemodialysis: randomized double blind clinical trial

### Public title

Probiotics and children under hemodialysis treatment

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Hemodialysis Patients during study period Two weeks after Discontinue antibiotics Two weeks after resolving acute inflammatory settings Two weeks after Discontinue probiotics

#### Exclusion criteria:

Patients with Chronic Inflammatory Setting like glumerolonephritis or nephrotic syndrome Patients received antibiotic or under inflammatory setting like polmunary infection or gastroenteritis Candidate for transplantation Receiving immuno-suppressive drugs specially steroids Receiving probiotics for any reason

### Age

From **4 years** old to **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **20**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization based on envelops Allocation Concealment Sequentially numbered, opaque, sealed envelopes

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Blinding for patients performed based on placebo drugs which is based on placebo which is same in color, form and size Physician is not informed about allocation in groups Data analyzer do not know about groups

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Tohid Square, Taheri St. Shahid Gharani St. 6

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91388-13944

#### Approval date

2018-04-21, 1397/02/01

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.204

## Health conditions studied

### 1

#### Description of health condition studied

Pediatric under hemodialysis treatment

#### ICD-10 code

N18

#### ICD-10 code description

Chronic kidney disease (CKD)

## Primary outcomes

### 1

#### Description

total Antioxidant Capacity

#### Timepoint

before and after intervention

#### Method of measurement

ELISA

### 2

#### Description

Nuclear Factor-kappa B

#### Timepoint

before and after intervention

#### Method of measurement

ELISA

### 3

#### Description

vascular cell adhesion molecule - 1

#### Timepoint

before and after intervention

#### Method of measurement

ELISA

## Secondary outcomes

1

### Description

### Timepoint

### Method of measurement

2

### Description

### Timepoint

### Method of measurement

## Intervention groups

1

### Description

Intervention group: Probiotic Intervention group receive probiotics Probiotic contain following strains :  
Lactobacillus casei ,Lactobacillus acidophilus ,  
Lactobacillus rhamnosus , Lactobacillus bulgaricus,  
Bifidobacterium breve , Bifidobacterium longum ,  
Streptococcus thermophilus in the count of 10<sup>9</sup> CFU in  
500 mg tablet from Zist Takhmir. Because these Bactria  
remain in the intestine and not absorb, nothing uptake  
during dialysis

### Category

Treatment - Other

2

### Description

Control group: placebo same in form, color and size

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Doctor Sheikh Hospital

#### Full name of responsible person

Dr Mitra Naseri

#### Street address

Tohid Sqr., Taheri St., Gharani St., 6

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91388-13944

#### Phone

+98 51 3841 2081

#### Email

presidentoffice@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr. Tafaghodi

#### Street address

Razavi Khorasan, Mashhad, Daneshgah St.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91388-13944

#### Phone

+98 51 3841 2081

#### Fax

+98 51 3841 3006

#### Email

presidentoffice@mums.ac.ir

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

-

### 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Mitra Naseri

#### Position

Pediatric Nephrologist

#### Latest degree

Specialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Mashhad, Daneshgah St.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91388-13944

**Phone**

+98 51 3841 2081

**Email**

NaseriM@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Bahareh Imani

**Position**

Pediatrician

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Mashhad, Daneshgah St.,

**City**

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**Province**

Razavi Khorasan

**Postal code**

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ImaniBH@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ehsan Ghaedi

**Position**

Nutritionist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Keshavarz Blvd., TUMS

**City**

Tehran

**Province**

Tehran

**Postal code**

14155-6617

**Phone**

+98 21 61111

**Email**

ehsanghaedi073@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

only with permission with supporter organization and also ethics committee would be shared.

**Study Protocol**

No - There is not 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**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available