

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of probiotic supplementation on patients' Hemoglobin with chronic Renal failure on Hemodialysis,

#### Protocol summary

##### Summary

The purpose of this study is "determination of the effect of probiotic supplementation on patients' Hemoglobin with chronic Renal failure on Hemodialysis. The study is a double blind intervention study with random allocation that it done in two Hemodialysis center. 36 patients are allocated randomly in two intervention and control groups (each groups 18 patients). The main inclusion criteria includes: Hemoglobin concentration <11g/dL in at least 3 episode; CRP more than 10 mg/ lit; Erythropoietin therapy for at least 4 weeks; Hemodialysis treatment for at least 6 months; 3 times dialysis per week and 4 hours per session; No surgery or bleeding in the last 3 months; Absence of active infection; No Consumption antibiotics in 10 days ago; No Hospitalization; Exclusion criteria: Antibiotic therapy during the study; Hospitalization; No Patient's tendency to stay in study; Bleeding during the study; The patients in intervention groups will receive oral probiotic supplement capsules 500mg per day after a meal for 12 weeks. The Patients in control group will receive one oral Placebo capsules per day for 12 weeks after a meal. Hemoglobin, CRP, were measured Before the intervention and three episode after intervention With each month interval and then compare groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013072710325N2**  
Registration date: **2015-01-09, 1393/10/19**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-09, 1393/10/19

#### Registrant information

##### Name

Gholamreza Mahmoodi Shan

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 1442 6900

##### Email address

mahmoudi@goums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Golestan University of Medical Sciences, Gorgan, Iran.

#### Expected recruitment start date

2014-08-23, 1393/06/01

#### Expected recruitment end date

2014-11-22, 1393/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of probiotic supplementation on patients' Hemoglobin with chronic Renal failure on Hemodialysis,

#### Public title

The effect of probiotic supplementation on patients' Anemia with chronic Renal failure on Hemodialysis.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Over 17 years old; Both sexes; Erythropoietin therapy for at least 4 weeks; Hemodialysis treatment for at least 6 months; 3 times dialysis per week and 4 hours per session; Hemoglobin concentration

<11g/dL in at least 3 episode; CRP more than 10 mg/ lit; No sever hyperparathyroidism; No surgery or bleeding in the last 3 months; Lack of Hemoglobin disorder including: Thalassemia or Sickle cell anemia; Lack of iron deficiency; Lack of folate and vitamin B12 deficiency; Absence of active infection; Lack of immune disorders such as Lupus erythematosus; Absence of malignancy; No Alcohol consuming; No Consumption antibiotics in 10 days ago; No Consumption corticosteroids; Lack of viral infections: AIDS; No Hospitalization; Exclusion criteria: Antibiotic therapy during the study; Hospitalization; Blood transfusion during the study; Surgery during the study; Change in drug program that it is effective on the anemia; Change in dialysis program; No Patient's tendency to stay in study; Malignancy diagnosis during the study; The presence of bleeding disorders during the study;

**Age**

From **17 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **36**

**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**

Ethical Committee Golestan University of Medical Sciences

**Street address**

Deputy of Research and Technology, Golestan University, Shastkola

**City**

gorgan

**Postal code****Approval date**

2014-06-08, 1393/03/18

**Ethics committee reference number**

562089303182

**Health conditions studied****1****Description of health condition studied**

End stage kidney disease on hemodialysis

**ICD-10 code**

N18.5

**ICD-10 code description**

End stage kidney disease

**Primary outcomes****1****Description**

Hemoglobin measurement

**Timepoint**

Before the intervention and three episode after intervantion With each month interval

**Method of measurement**

Laboratory equipment.

**Secondary outcomes****1****Description**

Quantitative CRP

**Timepoint**

Before the intervention and three episode after intervantion With each month interval

**Method of measurement**

Laboratory equipment.

**2****Description**

Blood presure

**Timepoint**

Three months before and three months after the intervention

**Method of measurement**

manometer

**3****Description**

Defecation pattern

**Timepoint**

Before the intervention and after the intervention three times with an interval of one month

**Method of measurement**

Bristol scale and patient statement

**Intervention groups****1****Description**

The intervention group consisted of 18 patients that they will receive oral probiotic supplement capsule, 500 mg

per day for 12 weeks, after a meal.

**Category**

Treatment - Drugs

**2****Description**

The control group consisted of 18 patients that they will receive oral Placebo capsules, one number per day for 12 weeks, after a meal.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

5 AZAR Hospital

**Full name of responsible person**

zahra shariaty

**Street address**

5 AZAR Hospital, 5 AZAR Street

**City**

Gorgan

**2****Recruitment center****Name of recruitment center**

Imam Hossein Hospital

**Full name of responsible person**

zahra shariaty

**Street address**

Imam Hossein Hospital, Imam street

**City**

Shahrood

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Deputy of Research and Technology, Golestan University

**Full name of responsible person**

DR.masoud khoshnia

**Street address**

Deputy of Research and Technology, Golestan University, Shastkola

**City**

gorgan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research and Technology, Golestan University

**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**

Golestan University of Medical Sciences

**Full name of responsible person**

zahra shariaty

**Position**

Ms Student of Critical Nursing Care

**Other areas of specialty/work****Street address**

Bouyeh School of Nursing & Midwifery, Golestan University of Medical Sciences

**City**

gorgan

**Postal code****Phone**

+98 17 3242 1660

**Fax****Email**

zshariaty@ymail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Gholamreza Mahmoodi Shan

**Position**

PhD, Assistant Professor

**Other areas of specialty/work****Street address**

Bouyeh School of Nursing & Midwifery, Golestan University of Medical Sciences, Shastkola

**City**

Gorgan

**Postal code****Phone**

+98 17 3242 1660

**Fax****Email**

mahmoodigh@yahoo.com;

mahmoodigh1392@Goums.ac.ir

**Web page address****Person responsible for updating data****Contact**

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

DR.Gholamreza Mahmoodi Shan

**Position**

PhD, Assistant Professor

**Other areas of specialty/work****Street address**

Bouyeh School of Nursing & Midwifery, Golestan  
University of Medical Sciences, Shastkola

**City**

Gorgan

**Postal code****Phone**

+98 17 3242 1660

**Fax****Email**

mahmoodigh@yahoo.com;

mahmoodigh1392@Goums.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*