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 allocted randomly in two intervention and control groups (each groups18 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: Antibiotictherapy 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 intervantion 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

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Gholamreza Mahmoodi Shan
Name of organization / entity
Golestan University of Medical Sciences
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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 sexess; 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 andTechnology, 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 andTechnology, 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

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Person responsible for scientific inquiries

Contact

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Position

PhD, Assistant Professor

Other areas of specialty/work

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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