

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of probiotic (*Saccharomycesboulardi*) on uremic toxins and quality of life in patients with chronic hemodialysis.

Protocol summary

Study aim

Effect of Probiotic on uremic toxins and quality of life in hemodialysis patients

Design

Trial has one group and intervention is the same for everyone

Settings and conduct

Sixty patients from chronic hemodialysis patients are selected from the hemodialysis center of Sina Hospital in Tabriz based on inclusion and exclusion criteria. Before starting the study, quality of life and assessment of the parameters listed above will be measured by taking 5cc of complete blood and then patients will receive 1 Daily Yeast capsule each day for 4 months. At the end of the study, measurements of these parameters and patient's quality of life will be re-evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Beginning of hemodialysis from previous 3 months and three times a week; The ability to understand and sign the consent form; Use of biocompatible dialysis membrane; Properly functioning arteriovenous fistula or catheter Exclusion criteria: Pregnancy and lactation; Use of broad-spectrum antibiotics in the last 3 months or now; Allergy to probiotics, The presence of any chronic, active, uncontrolled or severe chronic inflammatory disease (autoimmune diseases, connective tissue disease, malignancy, HIV, liver disease and pulmonary disease); chronic or acute infection in a recent month; Co-administration in another trial; A history of stroke or myocardial infarction in the last 3 months; Receiving medications which are effective on inflammatory factors (corticosteroids or other immunosuppressive drugs, nonsteroidal anti-inflammatory drugs, contraceptives, pentoxifylline)

Intervention groups

Intervention group: Consists of 60 hemodialysis patients receiving 1 Daily Yeast 500mg produced by Zist takhmir factory once daily for 4 months

Main outcome variables

Serum Concentration of Indoxyl sulfate, p-Cresyl Sulfate, p-cresol and Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N4**

Registration date: **2020-02-07, 1398/11/18**

Registration timing: **retrospective**

Last update: **2020-02-07, 1398/11/18**

Update count: **0**

Registration date

2020-02-07, 1398/11/18

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 1315

Email address

gharekhania@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-03, 1398/01/14

Expected recruitment end date

2019-06-04, 1398/03/14

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of probiotic (Saccharomycesboulardi) on uremic toxins and quality of life in patients with chronic hemodialysis.

Public title
The effect of probiotic on uremic toxins and quality of life in chronic hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Begining of hemodialysis from previous 3 months for three times a week Ability to understand and sign a consent form Use of biocompatible dialysis membrane Properly functioning arteriovenous fistula or catheter
Exclusion criteria:
Pregnancy and lactation Use of broad-spectrum antibiotics in the last 3 months or now Allergy to probiotics The presence of any chronic, active, uncontrolled or severe chronic inflammatory disease (autoimmune diseases, connective tissue disease, malignancy, HIV, liver disease and pulmonary disease) The presence of chronic or acute infection in a recent month Concurrently presence in another trial (drug or supplement) A history of stroke or myocardial infarction in the last 3 months Receiving medications which are effective on inflammatory factors (corticosteroids or other immunosuppressive drugs, nonsteroidal anti-inflammatory drugs, contraceptives, pentoxifylline)

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Center of Research and Technology, No 2 Central Building , Tabriz University of Medical Sciences , Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2019-01-07, 1397/10/17

Ethics committee reference number

IR.TBZMED.REC.1397.784

Health conditions studied

1

Description of health condition studied

hemodialysis patients

ICD-10 code

Z49.01

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

Serum level of Indoxyl Sulphate

Timepoint

Before intervention-At the end of intervention

Method of measurement

ELISA kit

2

Description

Serum level of P-cresyl sulphate

Timepoint

Before intervention-At the end of intervention

Method of measurement

ELISA kit

3

Description

Serum level of P-cresol

Timepoint

Before intervention-At the end of intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention-At the end of intervention

Method of measurement

Short form (36) quality of life survey

Intervention groups

1

Description

Intervention group: The treatment group consists of 60 patients receiving Daily Yeast 500 mg produced by Zist takhmir factory, once daily for 4 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Afshin Gharekhani

Street address

Sina Medical Research & Training Hospital, between Shahid montazeri & Hafez squares, Azadi Street, Tabriz

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5163639888

Phone

+98 41 3549 8342

Email

gharekhanian@tbzmed.ac.ir

Web page address

<https://sinahosp.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Abolghasem Jouyban

Street address

Drug Applied Research Center Medical Research and Development Complex, Daneshgah St., Tabriz-Iran

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gharekhanian@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Afshin Gharekhani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available