

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of lactulose on administration on nitrogen waste products in patients with chronic renal failure

#### Protocol summary

##### Summary

The aim of the present study is to assess the effect of lactulose prebiotic on nitrogen waste products in patients with chronic renal failure (CRF). This study would be a randomized placebo-controlled single-center clinical trial. The inclusion criteria would be the patients with stages 3 and 4 of CRF, the patients who are older than 18 years of age and the patients who have consent to continue the study. The exclusion criteria would be the history of any probiotic, sinbiotic and antibiotic use during one month prior to the study, patients with intolerance to lactulose or patients how create complications. We will randomly select 40 patients after consideration of all inclusion and exclusion criteria. The entire patients will receive 30cc lactulose suspension three times a day for two months. A blood sample will be taken from the study patients before the initiation of lactulose therapy, after two-month therapy and one month later than two-month therapy. Biochemical parameters will include levels of sodium, potassium, hemoglobin, hematocrit, blood urea nitrogen (BUN), creatinine, C-reactive protein (CRP), P-Cresol, Indoxyl Sulfate,  $\beta$ -2 microglobulin and parathyroid hormone (PTH). White blood cell (WBC) count will also be considered.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105316666N1**

Registration date: **2012-01-07, 1390/10/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-01-07, 1390/10/17

#### Registrant information

##### Name

Bitra Rahbari

##### Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 5921

##### Email address

rahbarib@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz University Of Medical Sciences and Health Services

#### Expected recruitment start date

2011-06-22, 1390/04/01

#### Expected recruitment end date

2011-08-22, 1390/05/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of lactulose on administration on nitrogen waste products in patients with chronic renal failure

#### Public title

The effect of lactulose on administration on nitrogen waste products

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria :1)The patients with stages 3 and 4 of CRF 2The patients who are older than 18 years of age3)

The patients who have consent to continue the study.  
Exclusion criteria:1) History of any probiotic, sinbiotic and antibiotic use during one month prior to the study2) patients with intolerance to lactolose or patients how create complications.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

0

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**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**

Tabriz University Of Medical Sciences and Health Services

**Street address**

Tabriz University Of Medical Sciences and Health Services, Golgasht Ave, Tabriz

**City**

Tabriz

**Postal code**

5166614756

**Approval date**

2011-06-14, 1390/03/24

**Ethics committee reference number**

5/4/2332

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

Chronic Renal Failure stages 3

**ICD-10 code**

N18.3

**ICD-10 code description**

Moderate Chronic Renal Failure (stage 3)

**2****Description of health condition studied**

Chronic Renal Failure (stage 4)

**ICD-10 code**

N18.4

**ICD-10 code description**

Severe Chronic Renal Failure (stage 4)

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

p-cresyl sulfate

**Timepoint**

at the end of the study and 1 month after the study

**Method of measurement**

at the end of the study and 1 month after the study

**2****Description**

Indoxyl sulfate

**Timepoint**

at the end of the study and 1 month after the study

**Method of measurement**

High Performance Liquid Chromatography = HPLC

**3****Description**

Advanced Glycation End (AGE) Products

**Timepoint**

at the end of the study and 1 month after the study

**Method of measurement**

High Performance Liquid Chromatography = HPLC

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

C-Reactive Protein = CRP

**Timepoint**

at the end of the study and after 1 month

**Method of measurement**

Standard lab test

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

Lactolose suspension 30 ml/min three times a day for two months

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Tabriz Emam Reza Hospital

**Full name of responsible person**

Dr.Bita Rahbari

**Street address**

Emam Reza Hospital , Golgasht Ave, Tabriz

**City**

Tabriz

Tabriz

**Postal code**

5166614756

**Phone**

+98 41 1335 5921

**Fax**

+98 41 1335 5944

**Email**

Rahbarib@tbzmed.ac.ir

**Web page address**

www.tbzmed.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tabriz University Of Medical Sciences and Health Services

**Full name of responsible person**

Miss Maghami

**Street address**

Tabriz University Of Medical Sciences and Health Services, Golgasht Ave, Tabriz

**City**

Tabriz

**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 and Health Services

**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**

Tabriz University Of Medical Sciences and Health Services

**Full name of responsible person**

Dr.Bita Rahbari

**Position**

Resident Of Internal Medicin

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

Tabriz University Of Medical Sciences and Health Services , Golgasht Ave, Tabriz

**City**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Hamid T. Khosroshahi

**Position**

MD, Subspeciality in Nephrology

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

Department of Internal Medicine, Emam Reza Hospital, Golgasht St.

**City**

Tabriz

**Postal code**

5166614756

**Phone**

+98 41 1337 8093

**Fax**

+98 41 1337 8093

**Email**

drtayebikh@yahoo.com

**Web page address**

www.tbzmed.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University Of Medical Sciences and Health Services

**Full name of responsible person**

Dr.Bita Rahbari

**Position**

Resident Of Internal Medicine

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

Tabriz University Of Medical Sciences and Health Services , Golgasht Ave, Tabriz

**City**

Tabriz

**Postal code**

5166614756

**Phone**

+98 41 1335 5921

**Fax**

+98 413355944

**Email**

Rahbarib@tbzmed.ac.ir

**Web page address**

www.tbzmed.ac.ir

## 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*