

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, β -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

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Name of organization / entity

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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

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

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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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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