Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of Lactulose effects on intestinal probiotics and blood glucose in type 2 diabetic patients.

Protocol summary

Summary

The aim of this study is to investigate the effects of lactulose on probiotic bacteria status and blood sugar in type 2 diabetic patients. Forty patients will be randomly assigned into intervention and control groups, each containing 20 subjects. Before and after end of the study blood and stool samples will be obtained. Hb A1C; blood glucose levels and probiotic bacteria colony count of 2 grams of stool will be measured. Inclusion criteria: type 2 diabetes; age between 30 to 70 years; HbA1c 7 to 9. Exclusion criteria: antibiotic use; presence of acute and chronic gastrointestinal diseases leading to intestinal dysfunction; HbA1c below 7 or above 9% ; the need to change medication or diet during the study; use of medications affecting bowel function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210193565N7**
Registration date: **2014-10-08, 1393/07/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-08, 1393/07/16

Registrant information

Name
Akbar Aliasgarzadeh
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2015-01-05, 1393/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Lactulose effects on intestinal probiotics and blood glucose in type 2 diabetic patients.

Public title

Lactulose effects on intestinal probiotics and blood glucose in diabetic patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: type II diabetes; age between 30 to 70 years; HbA1c 7 to 9. Exclusion criteria: antibiotic use; presence of acute and chronic gastrointestinal diseases leading to intestinal dysfunction; HbA1c below 7 or above 9%; need to change medication or diet during the study; use of medications affecting bowel function such as drugs for peptic ulcers, probiotics, laxatives; no history of surgery on gastrointestinal tract and liver; the absence of other systemic diseases affecting the gastrointestinal tract such as uncontrolled hypothyroidism, renal failure, liver disease and advanced heart failure; lack of consent to participate in the study.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Central building II ,Third floor, Golgasht Street,Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2014-08-04, 1393/05/13

Ethics committee reference number

9371

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Blood glucose levels

Timepoint

Baseline and three months after starting the study.

Method of measurement

Paraclinical

2

Description

Hemoglobin A1C

Timepoint

Baseline and three months after starting the study

Method of measurement

Paraclinical

3

Description

Stool probiotic bactria count

Timepoint

Baseline and three months after starting the study.

Method of measurement

Culture and colony count

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the intervention group receive 20,30 cc lactulose daily fo 3 months .

Category

Treatment - Drugs

2

Description

patients in control group receive their routine diabetes treatment without lactulose

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Akbar Aliasgharzadeh

Street address

Imam Reza hospital, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Farhoudi

Street address

Central building II,Third floor, Golgasht Street,Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of Tabriz University of Medical Sciences

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

Full name of responsible person

Dr. Akbar Asgharzadeh

Position

Associate Professor, Endocrinologist

Other areas of specialty/work

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Contact

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Person responsible for updating data

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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