

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7850

##### Email address

asgharzadeha@tbzmed.ac.ir

##### 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 bacteria 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****Street address**

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### Person responsible for scientific inquiries

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Asgharzadeh

**Position**

Associate Professor, Endocrinologist

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### Person responsible for updating data

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Arash Khayati

**Position**

MD, Resident of Internal Medicine

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arash.khayati@yahoo.com

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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*