

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Inullin supplementation on expression of KLF5 in Peripheral Blood Mononuclear Cell and pelasma levels miR-375 in patients with type 2 diabetes

#### Protocol summary

##### Summary

This study with The aim of inulin supplementation effect on KLF5(Krüppel-like factor 5) expression in mononuclear cells and plasma levels of miR-375 on 46 patients with type 2 diabetes that patients randomly divided into two groups of 23 .The first group (intervention) will be administered with 10 g per day of inulin powder divided two portions accompanied by main meals for 6 weeks. And the control group will be administered with 10 g per day placebo (corn starch) divided two portions accompanied by main meals for 6 week.All patients will be selected of Rohzende2 health care center in Shabestar.inclusion criteria for this study include:The diagnosis of type 2 diabetes; Aged 30 to 50 years; body mass index greater than 25 and less than 35 and Exclusion criteria include: kidney disease; liver failure; heart failure; rheumatic diseases inflammatory diseases of the gastrointestinal tract; lactose intolerance; insulin injection and drugs Consumption: estrogen, progesterone, corticosteroids; smoking; breast feeding and pregnancy; vitamin, minerals,omega-3 and antibiotics supplementation for three weeks before the start of the study will be considered.Before and after treatment from all of participants blood samples will be taken.And the expression of KLF5 and mir-375 all patients before and after supplementation will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201610212017N31**  
Registration date: **2016-12-19, 1395/09/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-19, 1395/09/29

##### Registrant information

###### Name

Alireza Ostadrahimi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7580

###### Email address

ostadrahimi@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

vice-chancellor for research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-09-19, 1395/06/29

##### Expected recruitment end date

2018-09-20, 1397/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Inullin supplementation on expression of KLF5 in Peripheral Blood Mononuclear Cell and pelasma levels miR-375 in patients with type 2 diabetes

##### Public title

The effect of Inullin supplementation on expression of

KLF5 in Peripheral Blood Mononuclear Cell and plasma levels miR-375 in patients with type 2 diabetes

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

inclusion criteria included: The diagnosis of type 2 diabetes; aged 30 to 50 years; body mass index greater than 25 and less than 35 Exclusion criteria included: kidney disease; liver failure; heart failure; rheumatic diseases inflammatory diseases of the gastrointestinal tract; lactose intolerance; insulin injection and drugs Consumption: estrogen, progesterone, corticosteroids; smoking; breast feeding and pregnancy; vitamin, minerals, omega-3 and antibiotics supplementation for three weeks before the start of the study

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 46

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **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**

Third Floor, Central Building(2), Tabriz University of Medical Sciences, Golgasht Street Tabriz

##### **City**

Tabriz

##### **Postal code**

00984133344280

#### **Approval date**

2016-09-26, 1395/07/05

#### **Ethics committee reference number**

IR.TBZMED.REC.1395.671

## **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**

Mir-375

#### **Timepoint**

Before and After

#### **Method of measurement**

Real-Time

## **Secondary outcomes**

### 1

#### **Description**

KLF5

#### **Timepoint**

Before and After

#### **Method of measurement**

Real-Time

## **Intervention groups**

### 1

#### **Description**

Intervention Groups: Two Oral Dose of 5 g of Inulin

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: Two Oral Dose 5 g Starch Corn

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health Center Rvzhndh 2

##### **Full name of responsible person**

Neda Roshanravan

##### **Street address**

Imam Khomeini Avenue, Shabestar, Tabriz

##### **City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-Chancellor for Research of Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Ostadrahimi

**Street address**

East Azarbaijan

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-Chancellor for Research 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**

Alireza Ostadrahimi

**Position**

Supervisor

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## Person responsible for scientific

## inquiries

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

Nutrition Faculty, Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Ostadrahimi

**Position**

Proffesor

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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*