Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 adminestrated with 10 g per day of inullin powder divided two portions accompanied by main meals for 6 weeks. And the control group will be adminestrated 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

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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 pelasma levels miR-375 in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria included:The diagnosis of type2 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

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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

Befor 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

Healt Center Rvhzndh 2

Full name of responsible person

Neda Roshanravan

Street address

Imam Khomeini Avenue, Shabestar,Tabriz

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Shabestar

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
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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

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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