# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

# The effect of sodium butyrate and inulin supplementation solo and simultaneously on glycemic index, Txnip gene expression and circulating levels of GLP-1, miR-204, miR-200c and miR-21 in patients with type 2 diabetes

## Protocol summary


**Summary**

(1) Objectives: The effect of sodium butyrate and inulin supplementation solo and simultaneously on glycemic index, Txnip gene expression and circulating levels of GLP-1, miR-204, miR-200c and miR-21 in patients with type 2 diabetes (2) Design: In this clinical trail, 60 patients with type 2 diabetic patients will be selected and randomly divided into 4 groups of 15 individuals. (3) Setting and conduct: After random allocation each patient will receive proprietary supplement for 45 days. (4) Participants including major eligibility criteria: Inclusion criteria included a diagnosis of type 2 diabetes; aged 30 to 50years; 27 <BMI range<35 Exclusion criteria included: kidney problems; liver failure, heart failure; rheumatic diseases and inflammatory diseases of the gastrointestinal tract; insulin injections and drugs; estrogen; progesterone; corticosteroids; smoking; breast feeding and pregnancy; taking vitamin supplements; minerals; omega-3 and antibiotics for three weeks before the study. (5) Intervention: Group 1 will receive sodium butyrate capsules (BodyBio) for 6 weeks as intervention drug as well as 5mg starch powder as placebo . Group 2 will consume inulin powder in the amount of 10 grams per day divided into two meals daily and 6 capsules 500 mg of starch as placebo. Group 3 devoted to the concomitant use of inulin powder and sodium butyrate capsules and Group 4 as the control group will receive placebo in the form of cap and powder. (6) main outcome measures (variables): Before and after the intervention of all participants will be received stool and blood samples. Frequency of Akkermansia muciniphila bacteria in stool before and after supplementation, serum levels of fasting glucose, insulin, HbA1C index, blood sugar levels after two hours eating breakfast, as well as the Txnip (Thioredoxin-interacting protein) gene expression and plasma levels of GLP-1( Glucagone like peptide 1), miR-204, miR-200c and miR-21 in all patients before and after supplementation will be evaluated.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201605262017N29**
Registration date: **2016-12-18, 1395/09/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-12-18, 1395/09/28

**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, Tabriz university of medical sciences

**Expected recruitment start date**

2016-11-21, 1395/09/01

**Expected recruitment end date**

2017-01-19, 1395/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of sodium butyrate and inulin supplementation solo and simultaneously on glycemic index, Txnip gene expression and circulating levels of GLP-1, miR-204, miR-200c and miR-21 in patients with type 2 diabetes

**Public title**

The effect of sodium butyrate and inulin supplementation solo and simultaneously on glycemic index, Txnip gene expression and circulating levels of GLP-1, miR-204, miR-200c and miR-21 in patients with type 2 diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Major inclusion criteria included a diagnosis of type 2 diabetes; aged 30 to 50years; range 27 <BMI <35 Major exclusion criteria included: kidney problems; liver failure; heart failure; rheumatic diseases and inflammatory diseases of the gastrointestinal tract; insulin injections and drugs; estrogen; progesterone ; taking vitamin supplements; minerals; omega-3 and antibiotics for three weeks before the study

**Age**

From **30 years** old to **50 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double 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**

Azadi St. Attar Nishabouri Ave

**City**

Tabriz

**Postal code**

5166614711

**Approval date**

2016-10-10, 1395/07/19

**Ethics committee reference number**

IR.TBZMED.1395.778

## Health conditions studied

### 1

**Description of health condition studied**

Diabetes mellitus Type 2

**ICD-10 code**

E10, E11,

**ICD-10 code description**

Diabetes mellitus

## Primary outcomes

### 1

**Description**

Txnip Gene

**Timepoint**

Before & after intervention

**Method of measurement**

Real-time PCR

### 2

**Description**

level of GLP-1

**Timepoint**

Before & after intervention

**Method of measurement**

Elisa test

### 3

**Description**

levels of mir-204

**Timepoint**

Before & after intervention

**Method of measurement**

Real-time PCR

### 4

**Description**

Levels of mir-200c

**Timepoint**

Before & after intervention

**Method of measurement**

Real-time PCR

**5**

**Description**
Levels of mir-21
**Timepoint**
Before & after intervention
**Method of measurement**
Real-time PCR

## Secondary outcomes

**1**

**Description**
fasting blood glucose
**Timepoint**
before & after intervention
**Method of measurement**
Enzymatic assay

**2**

**Description**
Blood sugar 2 hpp
**Timepoint**
before & after intervention
**Method of measurement**
Enzymatic assay

**3**

**Description**
fasting Insulin
**Timepoint**
before & after intervention
**Method of measurement**
Elisa

**4**

**Description**
HbA1C
**Timepoint**
before & after intervention
**Method of measurement**
Kit

**5**

**Description**
lipid profile
**Timepoint**
before & after intervention
**Method of measurement**
Enzymatic assay

**6**

**Description**
Energy and macronutrients
**Timepoint**
before & after intervention
**Method of measurement**
3 days recall

**7**

**Description**
abundance of Akkermansia muciniphila bacteria in stool samples
**Timepoint**
before & after intervention
**Method of measurement**
colony count

## Intervention groups

**1**

**Description**
Group 1 (intervention group) consume 6 capsules of 100 mg of sodium butyrate capsules and 5 mg starch powder as placebo for 6 weeks with meals daily.
**Category**
Treatment - Drugs

**2**

**Description**
Group 2 consume inulin powder (chicory root extract) 10 g and 6 starch capsules 500 mg as placebo per day for 6 weeks.
**Category**
Treatment - Drugs

**3**

**Description**
Group 3 devoted to the concomitant use of inulin powder and capsules sodium butyrate (10 g inulin powder and sodium butyrate 6 capsules 100 mg) for 6 weeks.
**Category**
Treatment - Drugs

**4**

**Description**
Group 4 (control group) consume 6 capsules 500 mg starch as well as 5 mg starch powder as placebo for 6 weeks.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Office
**Full name of responsible person**
Neda Roshanravan
**Street address**
Next to national bank branch, Pasdaran St, Shabestar, Iran

**City**
Shabestar

**2**

**Recruitment center**
**Name of recruitment center**
Rohzendeh2 health and therapetic center
**Full name of responsible person**
Neda Roshanravan
**Street address**
Emam Khomeini St, Shabestar, Iran
**City**
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**
Dr Alireza Ostadrahimi
**Street address**
Faculty of Nutrition, Azadi Ave, Golgasht Str, Tabriz, Iran
**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**
Neda Roshanravan
**Position**
Ph.D candidate
**Other areas of specialty/work**
**Street address**
Azadi Ave, Attar Nishabouri St, Tabriz, Iran
**City**
Tabriz
**Postal code**
5166614711
**Phone**
+98 41 3335 7581
**Fax**
**Email**
roshanravann@tbzmed.ac.ir;
neda.roshanravan10@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tabriz university of Medical Sciences
**Full name of responsible person**
Neda Roshanravan
**Position**
Ph.D candidate
**Other areas of specialty/work**
**Street address**
Nutrition Faculty, Attar Neyshaburi Street, Golgasht Avenue, Tabriz, Iran
**City**
Tabriz
**Postal code**
5166614711
**Phone**
+98 41 3335 7581
**Fax**
**Email**
ostadrahimi@tbzmed.ac.ir;
Roshanravann@tbzmed.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tabriz university of Medical Sciences
**Full name of responsible person**
Neda Roshanravan
**Position**
Ph.D candidate
**Other areas of specialty/work**
**Street address**
Nutrition Faculty, Attar Neyshaburi Ave, Golgasht St, Tabriz, Iran
**City**
Tabriz
**Postal code**
Iran
**Phone**
+98 41 4242 7330
**Fax**
**Email**
ostadrahimi@tbzmed.ac.ir;
roshanravann@tbzmed.ac.ir
**Web page address**

## 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*