Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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