

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of sodium butyrate supplementation on serum oxidative stress indices and gene expression level of pyroptosis related inflammatory factors in type 2 diabetic patients: A randomized, double-blind, placebo-controlled trial

#### Protocol summary

##### Study aim

This study will be done with the aim of investigating the effect of sodium butyrate supplementation on serum oxidative stress indices and gene expression level of pyroptosis related inflammatory factors in type 2 diabetic patients.

##### Design

In this double-blind randomized placebo-controlled parallel group clinical trial, 42 type 2 diabetic patients of both sexes will be randomly divided into 2 groups of 21 individuals.

##### Settings and conduct

The study will be conducted in the Nutrition Research Center of Tabriz University of Medical Sciences. Patients will be randomly assigned into 2 groups. The questionnaires of general information will be completed. After random allocation each patient will receive proprietary supplement for 6 weeks. Sodium butyrate and placebo packs will be encoded by the person responsible for preparation; investigators and patients will be blinded to the type of the supplement each group receives. Fasting blood samples will be collected at baseline and at the end of the study.

##### Participants/Inclusion and exclusion criteria

Major eligibility criteria: Ages between 30 to 50 years; Diagnosis of type 2 diabetes; BMI between 27 to 35 kg/m<sup>2</sup>. Exclusion criteria: chronic diseases; Kidney, liver and thyroid disorders; Rheumatic Diseases; Inflammatory diseases; Insulin injection, taking estrogenic drugs, progesterone & corticosteroids; Taking supplements, and antibiotics; Smoking; Pregnancy; lactation; menopause;

##### Intervention groups

Group 1 will receive sodium butyrate capsules (BodyBio) for 6 weeks at a daily dose of 600 mg in the form of capsules of 100 mg with food. Group 2, as a control group, will use 6 starch capsules daily as placebo.

##### Main outcome variables

Glycemic indexes; lipid profile; expression of TLR-4, NLRP3, ASC, Caspase-1, IL-1 $\beta$ , IL-18; glutathione peroxidase(GPx); Nitric oxide(NO) will be evaluated before and after the supplementation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090609002017N33**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

##### Registration date

2019-04-06, 1398/01/17

##### 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

##### Expected recruitment start date

2019-03-25, 1398/01/05  
**Expected recruitment end date**  
2019-05-15, 1398/02/25  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### Scientific title

The effect of sodium butyrate supplementation on serum oxidative stress indices and gene expression level of pyroptosis related inflammatory factors in type 2 diabetic patients: A randomized, double-blind, placebo-controlled trial

#### Public title

Effect of sodium butyrate in prevention and treatment of type 2 diabetes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Willingness to participate in the study Ages between 30 to 50 years (both sexes) Diagnosis of type 2 diabetes Body mass index (BMI) between 27 to 35 kg/m<sup>2</sup> People who control their diabetes just by using blood glucose lowering tablets.

##### Exclusion criteria:

Unwillingness to participate in the study Chronic diseases such as cardiovascular disorders and ... Kidney, liver and thyroid disorders Rheumatic Diseases Inflammatory diseases of the gastrointestinal tract or malabsorption, such as sprue and crows Insulin injection, taking estrogenic drugs, progesterone & corticosteroids Taking vitamin supplements; minerals; omega-3 and antibiotics for three weeks before the study Changes in diet and physical activity Smoking Having certain physiological conditions like pregnancy and lactation and menopause

#### Age

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

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **42**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Samples will be assigned to intervention and control groups by random blocking.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, investigator and participants will be unaware of the type of supplementation (sodium butyrate or placebo). The person responsible for the preparation of capsules' packs (a person completely

unrelated to the study) will be asked to assign a code to each of the two packages (sodium butyrate and placebo), and to keep the codes up to the end of the study and data analysis.

#### 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

3rd. Floor, Central Bldg. No.2, Golgasht st., Azadi Ave.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614776

#### Approval date

2019-03-11, 1397/12/20

#### Ethics committee reference number

IR.TBZMED.REC.1397.1036

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes mellitus Type 2

#### ICD-10 code

E10, E11,

#### ICD-10 code description

Diabetes

## Primary outcomes

### 1

#### Description

TLR-4 expression

#### Timepoint

Before & after the intervention

#### Method of measurement

Real-time PCR

### 2

#### Description

NLRP3 expression

#### Timepoint

Before & after the intervention  
**Method of measurement**  
Real-time PCR

### 3

**Description**  
Caspase-1 expression  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Real-time PCR

### 4

**Description**  
ASC expression  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Real-time PCR

### 5

**Description**  
IL-1 $\beta$  expression  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Real-time PCR

### 6

**Description**  
IL-18 expression  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Real-time PCR

### 7

**Description**  
Glutathion Peroxidase (GPx)  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Kit

### 8

**Description**  
Nitric Oxide (NO)  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Kit

### 9

**Description**  
Fasting Blood Glucose  
**Timepoint**  
Before & after the intervention

**Method of measurement**  
Enzymatic assay

### 10

**Description**  
Fasting Insulin  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
ELISA

### 11

**Description**  
HbA1c  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Kit

### 12

**Description**  
HOMA-IR  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
HOMA-IR formula: [fasting insulin ( $\mu$ U/ml)\*fasting glucose (mg/dL)]/ 405

### 13

**Description**  
Triglyceride  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Enzymatic method

### 14

**Description**  
HDL-Cholesterol  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Enzymatic method

### 15

**Description**  
Total Cholesterol  
**Timepoint**  
Before & after the intervention  
**Method of measurement**  
Enzymatic method

### 16

**Description**  
LDL-Cholesterol  
**Timepoint**  
Before & after the intervention

**Method of measurement**

Friedewald's formula:  $LDL = TC - [HDL + (TG/5)]$

**Secondary outcomes****1****Description**

Systolic Blood Pressure

**Timepoint**

Before & after the intervention

**Method of measurement**

Digital barometer

**2****Description**

Diastolic Blood Pressure

**Timepoint**

Before & after the intervention

**Method of measurement**

Digital barometer

**3****Description**

Energy and macro-nutrient intake

**Timepoint**

Before & after the intervention

**Method of measurement**

Questionnaire (3 days dietary record)

**4****Description**

Weight

**Timepoint**

Before & after the intervention

**Method of measurement**

scale

**5****Description**

Body Mass Index

**Timepoint**

Before & after the intervention

**Method of measurement**

BMI formula

**6****Description**

Waist circumference

**Timepoint**

Before & after the intervention

**Method of measurement**

Nonelastic flexible tape

**7****Description**

Hip circumferences

**Timepoint**

Before & after the intervention

**Method of measurement**

Nonelastic flexible tape

**8****Description**

Waist to Hip Ratio (WHR)

**Timepoint**

Before & after the intervention

**Method of measurement**

Calculation

**Intervention groups****1****Description**

Group 1 will receive sodium butyrate capsules (BodyBio) for 6 weeks at a daily dose of 600 mg in the form of capsules of 100 mg with meals.

**Category**

Treatment - Drugs

**2****Description**

Control group: Group 2 will use starch capsule as placebo for 6 weeks at a daily dose of 6 capsule with meals.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Roohzende Health and Therapeutic Center no.2

**Full name of responsible person**

Neda Roshanravan

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Emam Khomeini St.

**City**

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East Azarbaijan

**Postal code**

5381855785

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neda.roshanravan10@gmail.com

**Web page address****2****Recruitment center****Name of recruitment center**

AZAR Cohort recruitment center (Khamaneh Hospital's outpatient clinic)

**Full name of responsible person**

Alireza Ostadrahimi

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Sheikh Mohammad Khiabani st.

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**Postal code**

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ostadrahimi@tbzmed.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Nutrition Research Center, Tabriz University of  
Medical Science**Full name of responsible person**

Alireza Ostadrahimi

**Street address**5th Floor, Nutrition Faculty Bldg., Attar Neyshaburi st.,  
Golgashat ave.**City**

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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**Nutrition Research Center, Tabriz University of Medical  
Science**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Zeinab Khosravi

**Position**

MSc student in Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**Faculty of Nutrition, Tabriz University of Medical  
Science, Attar Neyshaburi st., Golgasht ave.**City**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Ostadrahimi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

MSc student in Nutrition

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**Other areas of specialty/work**

Nutrition

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Individual participant data that underlie the outcomes reported in this article, after deidentification (text, tables, figures, and appendices), Study Protocol, Statistical Analysis Plan, Clinical Study Report

**When the data will become available and for how long**

Beginning 6 months and ending 2 years following article publication

**To whom data/document is available**

Researchers who provide a methodologically sound proposal.

**Under which criteria data/document could be used**

The datasets are available from the corresponding author on reasonable request and to achieve aims in the approved proposal.

**From where data/document is obtainable**

Proposals should be directed to corresponding author.

**What processes are involved for a request to access data/document**

All data requests should be submitted to the corresponding author for consideration. To gain access, data requestors will need to sign a data access agreement.

**Comments**