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/m2. 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-1β, 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)

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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/m2 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 crowns 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-1β 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 (µU/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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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutrition Research Center, Tabriz University of Medical Science
Full name of responsible person
Alireza Ostadrahimi
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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
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Person responsible for updating data

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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