

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Effects of butyrate supplementation on plasma atherogenic index(AIP), serum level of hsCRP, expression level of adiponectin receptors(AdipoR1& R2), AMP activated protein kinase(AMPK) and uncoupling proteins(UCP2&3) genes in Obese individuals on a weight loss diet: A Randomized, Triple- Blind, Placebo- Controlled Clinical Trial

#### Protocol summary

##### Study aim

Determination of the effects of sodium butyrate supplementation on the atherogenic index of plasma(AIP), serum levels of hsCRP, the expression levels of adiponectin receptors(AdipoR1& R2), uncoupling proteins(UCP2&3) and peroxisome proliferator-activated receptor  $\alpha$  (PPAR $\alpha$ ) genes in Obese individuals

##### Design

A clinical trial with the control group, with parallel groups, triple-blind, randomized, phase 2 on 50 patients. For randomization, block design is used.

##### Settings and conduct

Referred to Nutrition Faculty of Tabriz University of Medical Sciences in 2021, selection of 50 patients based on inclusion and exclusion criteria, randomization into intervention and control groups. Blinding of patients and researchers, coding by a third party who does not know the details.

##### Participants/Inclusion and exclusion criteria

body mass index 30 to 40, both females and males, age between 18 to 60 years Non-inclusion criteria: unwillingness to continue the study, kidney diseases, liver failure, heart failure, rheumatic diseases, diabetes, malignancies, and gastrointestinal diseases, taking any supplements, taking weight-loss drugs and following a weight loss diet, history of obesity surgery, smoking, pregnancy, lactation, menopause

##### Intervention groups

The intervention group: one butyrate capsule of 600mg/day (made by Body Bio company, USA, containing 550 mg of butyrate and 50 mg sodium hydroxide, medium-chain triglycerides (MCT), hydroxypropyl methylcellulose, and purified water) for 60

days. The control group: one placebo capsule of 600 mg/day (compounds similar to supplement except for butyrate) for 60 days

##### Main outcome variables

Atherogenic index of plasma(AIP), serum levels of hsCRP, expression levels of adiponectin receptors(AdipoR1& R2), uncoupling proteins(UCP2&3) and peroxisome proliferator-activated receptor  $\alpha$  (PPAR $\alpha$ )

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190303042905N3**

Registration date: **2021-06-22, 1400/04/01**

Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**

Update count: **0**

##### Registration date

2021-06-22, 1400/04/01

##### Registrant information

##### Name

Parichehr Amiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 5503

##### Email address

amiriparichehr70@gmail.com

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2021-06-27, 1400/04/06

### Expected recruitment end date

2021-11-01, 1400/08/10

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

The Effects of butyrate supplementation on plasma atherogenic index(AIP), serum level of hsCRP, expression level of adiponectin receptors(AdipoR1& R2), AMP activated protein kinase(AMPK) and uncoupling proteins(UCP2&3) genes in Obese individuals on a weight loss diet: A Randomized, Triple- Blind, Placebo-Controlled Clinical Trial

## Public title

The Effects of sodium butyrate supplementation on obesity

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Body mass index (BMI) between 30-40 Both of genders female and male Age between 18-60 years old

### Exclusion criteria:

Unwillingness to participate in the study Kidney diseases liver failure heart failure rheumatic diseases diabetes malignancies, and gastrointestinal diseases Taking weightloss drugs and following a weight loss diet History of bariatric surgery Smoking Pregnancy, lactation, menopause

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Based on inclusion criteria, 50 patients will randomly allocated to placebo (n = 25) or intervention (n = 25) groups. Block design based on the combined analysis and using random allocation software(RAS)is used for randomization. In fact, according to the pattern and using two codes of A and B 6 groups with 4 blocks are

selected. This work is repeated in 2 steps. In the end, two A and B codes are assigned to the 2 last patients and the randomization is completed (50 patients).

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The researchers and patients will not inform of the contents of the packets. A third person of health care does the coding. This person will not aware of the details of the research trial.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Golghasht Street,Tabriz University of Medical Sciences, second central building,third floor

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Approval date

2021-05-31, 1400/03/10

#### Ethics committee reference number

IR.TBZMED.REC.1400.235

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

Gene expression level of AdipoR1& R2

#### Timepoint

Before the intervention and two months after the intervention

## Method of measurement

Real- time PCR

## 2

### Description

Gene expression level of AMPK

### Timepoint

Before the intervention and two months after the intervention

### Method of measurement

Real- time PCR

## 3

### Description

Gene expression level of UCP 2 & 3

### Timepoint

Before the intervention and two months after the intervention

### Method of measurement

Real- time PCR

## Secondary outcomes

## 1

### Description

Serum levels of hsCRP

### Timepoint

Before the intervention and two months after the intervention

### Method of measurement

ELISA kit

## 2

### Description

Atherogenic index of plasma(AIP)

### Timepoint

Before the intervention and two months after the intervention

### Method of measurement

based on formula:  $AIP = \log \left[ \frac{\text{triglycerides}}{\text{high density lipoprotein}} \right]$

## Intervention groups

## 1

### Description

Intervention group: one butyrate capsule of 600mg/day(made by Body Bio company, USA, containing 550 mg of butyrate and 50 mg sodium hydroxide, medium-chain triglycerides (MCT), hydroxypropyl methylcellulose, and purified water) for 60 days

### Category

Treatment - Other

## 2

### Description

Control group: Control group: one placebo capsule of 600 mg/day(compounds similar to supplement except for butyrate)

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Health centers of Tabriz University of Medical Sciences

#### Full name of responsible person

Neda Roshanravan

#### Street address

School of Nutrition and Food Sciences, Golgasht Street

#### City

Tabriz

#### Province

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#### Phone

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#### Email

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Samad Ghaffari

#### Street address

Cardiac Research Center-First Floor - Shahid Madani Cardiovascular Education and Research Center - Daneshgah St

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#### Province

East Azarbaijan

#### Postal code

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#### Phone

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#### Fax

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#### Email

ghafaris@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Parichehr Amiri

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**Ahvaz Jundishapur University of Medical Sciences,  
Golestan Ave, khuzestan, Ahvaz, Iran**City**

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

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Ph.D.

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Biochemistry

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

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**Full name of responsible person**

Parichehr Amiri

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**Ahvaz Jundishapur University of Medical Sciences,  
Golestan Ave, khuzestan, Ahvaz, Iran**City**

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**Phone**

+98 21 4568 9745

**Email**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**The person's information will be confidential and the  
results will be as collective statistics**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**This clinical trial will be a research article and its  
protocol, results report and statistical analysis will be  
published to be used by therapists and researchers.**When the data will become available and for how long**If the journal requests access to the data at any time, the  
data will be provided

**To whom data/document is available**

Journal editors and Reviewers

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

Sometimes for re-analysis or for use in meta-analysis studies

**From where data/document is obtainable**

Project manager

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

It should send an email to the project manager and after reviewing the reason for requesting the data, they will be sent

**Comments**