

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 α (PPAR α) 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 α (PPAR α)

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)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

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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 IPDThe 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/documentThis 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