Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Aug 2026

The Effects of butyrate supplementation on the expression levels of PGC-1α, PPARα and UCP1 genes, serum level of GLP-1, metabolic parameters, and anthropometric indices in obese individuals on a weight loss diet: A Triple- Blind, Randomized, Placebo- Controlled Clinical Trial.

Protocol summary

Study aim

Determination of the effects of butyrate supplementation on the expression levels of PGC-1α, PPARα and UCP1 genes, serum level of GLP-1, metabolic parameters, and anthropometric indices in obese individuals on a weight loss diet

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

Inclusion 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

weight, body mass index, waist circumference, waist circumference, fat mass, lean mass; serum level of GLP-1; gene expression of PGC-1α, PPARα, UCP1; lipid factors, fasting glucose, alanine aminotransferase, aspartate aminotransferase, insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042905N2**
Registration date: **2021-01-31, 1399/11/12**
Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**
Update count: **1**

Registration date

2021-01-31, 1399/11/12

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

2021-03-21, 1400/01/01

Expected recruitment end date
2021-11-21, 1400/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of butyrate supplementation on the expression levels of PGC-1α, PPARα and UCP1 genes, serum level of GLP-1, metabolic parameters, and anthropometric indices in obese individuals on a weight loss diet: A Triple- Blind, Randomized, Placebo-Controlled Clinical Trial.

Public title
Effect of butyrate in 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 Consumption of any product or supplement containing probiotics, prebiotics and antibiotics in the last 1 month Taking vitamin, fiber, omega-3, antioxidant supplements during the 3 weeks before and during the study Taking weight-loss drugs and following a weight loss diet for the past six months 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 packed envelopes 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 Ahvaz Jundishapur University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran
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Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2021-01-27, 1399/11/08
Ethics committee reference number
IR.AJUMS.REC.1399.845

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
Weight
Timepoint
Before the intervention and two months after the intervention
Method of measurement

Using scales

2

Description
Waist circumference
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using tape

3

Description
Body mass index(BMI)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
By dividing weight (kg) to height square (m2)

4

Description
Waist to hip ratio(WHR)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Waist circumference/hip circumference

5

Description
Fat mass(FM)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using bioelectrical impedence analyser

6

Description
Fat free mass(FFM)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using bioelectrical impedence analyser

7

Description
Serum level of GLP-1
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

8

Description
Gene expression of PGC-1α
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

9

Description
Gene expression of PPARα
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

10

Description
Gene expression of UCP1
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

11

Description
Serum level of LBP
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

12

Description
Gene expression of TNF-α
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

13

Description
Gene expression of TLR4
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

14

Description
Gene expression of NFkB

Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

15

Description
population of Lactobacilli in gut microbiota
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

16

Description
population of Bifidobacteria in gut microbiota
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

17

Description
population of Lachnospiraceae in gut microbiota
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Real time- PCR

18

Description
Malondialdehyde(MDA)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
MDA kit

19

Description
glutathione peroxidase(GPX)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
GPX kit

20

Description
superoxide dismutase (SOD)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
SOD kit

Secondary outcomes

1

Description
Serum levels of Triglyceride
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using enzymatic kit method

2

Description
Serum levels of High-Density Lipoprotein cholesterol (HDL-c)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using enzymatic kit method

3

Description
Serum levels of High-Density Lipoprotein cholesterol (LDL-c)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using enzymatic kit method

4

Description
Fasting blood sugar
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using enzymatic kit method

5

Description
Serum levels of alanine transaminase (ALT)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Using enzymatic kit method

6

Description
Serum levels of aspartate aminotransferase (AST)
Timepoint
Before the intervention and two months after the

intervention

Method of measurement

Using enzymatic kit method

7

Description

Serum levels of insulin

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kit

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

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Nutrition and Food Sciences, Tabriz University of Medical Sciences

Full name of responsible person

Maryam saghafi-asl

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Ahvaz 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 of Nutrition

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 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
Yes - There is 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