Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation the effect of postbiotic butyrate supplementation on the expression of circadian genes, inflammation, sleep quality and psychological factors in patients with ulcerative colitis

Protocol summary

Study aim

The aim of this study was to evaluate the effect of postbiotic butyrate supplementation on the expression of circadian genes, inflammation, sleep quality and psychological factors in patients with ulcerative colitis.

Design

In a randomized controlled clinical trial study of double blinded parallel in phase 4, 30 people were divided into two groups of intervention and control.

Settings and conduct

Thirty new patient in the active phase with low to moderate colitis severity will be selected for this study through colonoscopy from Namazi hospital. Patients are randomly divided into intervention or control groups. Participants receive butyrate or starch capsules, marked A or B to blind participants and staff, based on the assigned group. Anthropometric indices, questionnaires, blood samples, stool samples will be taken at start and the end of the study from the patients. To evaluate patients' diets, three 24-hour diet recalls will be taken during the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: New adult patients 20 to 60 years with low to moderate disease severity. Exclusion criteria: Patients with intestinal obstruction, fistula, cancer, type 2 diabetes, infectious diseases, pregnancy or lactation, use of antibiotics in the past two weeks and prebiotic or probiotic products, vitamin and mineral supplements in the past month and Psychological drugs, changes in the type or dose of drugs.

Intervention groups

Participants are divided into two groups of intervention and control. In the intervention group, people received butyrate and starch capsule at dose of 600 mg once a day for 12 weeks with dietary recommendations for UC in the intervention and control groups respectively.

Main outcome variables

The main primary variables in the present study were the expression of circadian rhythm genes including (CRY2, Bmal1 and CLOCK) and fecal calprotectin levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211214053401N1**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Donya Firoozi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of postbiotic butyrate supplementation on the expression of circadian genes, inflammation, sleep quality and psychological factors in patients with ulcerative colitis

Public title
Effect of butyrate in ulcerative colitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New case Mild to moderate UC Active phase of diseases
Exclusion criteria:
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Thirty eligible individuals are divided into 2 groups by block randomization method. The blocks are made by an out-of-study person and the assignment group is placed in a sealed envelope for each individual. After entering the study, by opening the envelope, the person will be informed of the assigned group, which are named with the letters A or B.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind randomized controlled trial, a person outside the study labels butyrate and placebo supplements with the letters A or B for blinding. Supplements and placebos are similar in appearance and physical properties. Assignment groups are also named based on the name assigned to the supplement and placebo. As a result, participants and researchers become blind. Also, people who evaluate the consequences and analyze the data will be blind to the groups. It should be noted that at the beginning of the study, participants are informed that they are in one of the supplement or placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Schools of Health, Nutrition and Food Sciences - Shiraz University of Medical Sciences (Research Eth
Street address
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Approval date
2021-10-17, 1400/07/25
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1400.037

Health conditions studied

1

Description of health condition studied
Ulcerative Colitis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Expression of circadian genes including (CRY2, Bmal1 and CLOCK)
Timepoint
At the beginning of the study and 12 weeks later (end of the study)
Method of measurement
Blood samples will be taken from patients to evaluate the expression of circadian rhythm genes. After isolation of peripheral blood mononuclear cells, the expression of circadian genes (CRY2, Bmal1 and CLOCK) will be evaluated by RT-PCR.

2

Description
Calprotectin
Timepoint
At the beginning of the study and 12 weeks later (end of the study)
Method of measurement
For determination of fecal calprotectin level, 20 g of fecal sample will be taken from patients in the early morning and fecal calprotectin level will be measured using

special commercial kits.

Secondary outcomes

1

Description
Serum level of hs-CRP
Timepoint
Beginning of study and 12 weeks later (end of study)
Method of measurement
ELIZA commercial kit

2

Description
Sleep quality
Timepoint
Beginning of study and 12 weeks later (end of study)
Method of measurement
PSQI questionnaire

3

Description
depression and anxiety
Timepoint
Beginning of study and 12 weeks later (end of study)
Method of measurement
HADS (Hospital anxiety depression scale) questionnaire

4

Description
Stress
Timepoint
Beginning of study and 12 weeks later (end of study)
Method of measurement
general health questionnaire

5

Description
Life quality
Timepoint
Beginning of study and 12 weeks later (end of study)
Method of measurement
IBDQ-9 self-management questionnaire

6

Description
AST and ALT
Timepoint
Beginning of study and 12 weeks later (end of study)
Method of measurement
commercial kit

Intervention groups

1

Description
Intervention group: The patients take butyrate capsules at a dose of 600 mg once a day for 12 weeks with dietary recommendations for IBD patients that take it with the main meal. Butyrate supplement is provided by Body bio company.
Category
Treatment - Drugs

2

Description
Control group: The patients take starch capsules at a dose of 600 mg once a day for 12 weeks with dietary recommendations for IBD patients that take it with the main meal.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Mohammad Kazem Hosseini Asl
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Sponsors / Funding sources

1

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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
Shiraz 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
Shiraz University of Medical Sciences
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Donya Firoozi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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