

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)

Phone

+98 71 3636 4883

Email address

donyafiroozi@gmail.com

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

School of nutrition and food sciences, Razi Boulevard

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

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

Street address

Namazi hospital, Namazi Square, Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶-۷۱۳۳۶

Phone

+98 61 3647 4332

Email

nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Jalil Masoumi

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

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

Full name of responsible person

Donya Firoozi

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

School of Nutrition and Food Sciences, Razi blv.,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶۷۱۳۴۸

Phone

+98 71 3725 1005

Email

donyafiroozi@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Jalil Masoumi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shiraz Medical Science Information Technology
Development Center, Neshat St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۷۴۸۵۳

Phone

+98 71 3233 2505

Email

masoumi7415@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Donya Firoozi

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

School of Nutrition and Food Sciences, Razi blv.,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Phone

+98 71 3725 1005

Email

donyafiroozi@gmail.com

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