Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Effect of Butyrate on anti inflammatory genes Sirt1 and Pgc1alpha and apoptosis gene Bax and Bcl2 in Ulcerative colitis patients

Protocol summary

Study aim

General purpose Determining the effect of postbiotic Butyrate supplementation on the expression of anti-inflammatory genes Sirt1 and Pgc1alpha and apoptosis genes Bax and Bcl2 and quality of life and anthropometric indicators in Ulcerative colitis patients. Functional goal Use of postbiotic Butyrate dietary supplement to improve inflammation and quality of life in patients with Ulcerative colitis.

Design

A clinical trial with a double-blind control group was randomized on 30 patients and block randomization was used for randomization.

Settings and conduct

Patients referred to Shiraz Faqihi Hospital with mild to moderately active ulcerative colitis. Blood samples, anthropometric indicators and IBDQ9 quality of life questionnaire will be taken from the participants at the beginning and end of the study. Finally, the expression level of Bax, Bcl2, Sirt1, genes will be measured by RT-PCR method. Participants will be divided using block randomization method and patient and researcher will be blinded in this study

Participants/Inclusion and exclusion criteria

Inclusion: Patients with mild to moderate Ulcerative colitis aged 18 to 60 years exclusion: pregnancy and breastfeeding and other gastrointestinal diseases and consumption of other probiotic and antibiotic supplements and changes in the process of taking drugs during the study

Intervention groups

The intervention group was supplemented with sodium Butyrate 600 mg per day for 12 weeks and the control group with starch 600 mg per day for 12 weeks.

Main outcome variables

The primary outcomes will be measuring the expression of Bax, Bcl2, Sirt1, and Pgc1alpha genes at the beginning and end of the study in both groups, and the secondary outcome will be the assessment of quality of life using the IBDQ9 questionnaire in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221215056828N1**
Registration date: **2023-09-03, 1402/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-03, 1402/06/12**
Update count: **0**

Registration date

2023-09-03, 1402/06/12

Registrant information

Name

Mohammad Vatanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-24, 1402/06/02

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Butyrate on anti inflammatory genes Sirt1 and Pgc1alpha and apoptosis gene Bax and Bcl2 in Ulcerative colitis patients

Public title
Investigating the effect of Butyrate on inflammatory genes and apoptosis in Ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male or female 18 to 60 years old Body mass index between 18.5 and 30 Estimating the severity of the disease based on the Mayo The severity of the disease is mild to moderate Patients with ulcerative colitis diagnosed by colonoscopy Informed consent from the patient Patients who are in the quiescent stage of the disease are included in the study, and patients who are in the acute stage of the disease are excluded. The patient should refrain from any self treatment and use of herbal medicines.

Exclusion criteria:
Patients with other gastrointestinal diseases including intestinal obstruction, fistula, celiac disease, cancer and infectious diseases Pregnancy and breastfeeding Use of antibiotic drugs and other probiotic products and vitamin and mineral supplements for the previous 2 months. History of hospitalization in the last 3 months Type 2 diabetes patients Acute stage of the disease Change in the process of drug consumption during the study Intensification of the disease during study The place of implementation of the study is Faqihi Hospital and Motahari Clinic of Shiraz University of Medical Sciences

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The use of block randomization method, eligible candidates are randomly divided into two groups through 5 blocks of six numbers, in each block there are three volunteers of the intervention group and three volunteers of the placebo group in different order.

Blinding (investigator's opinion)
Double blinded

Blinding description
By a third party who is not involved in the study and is completely unaware of the details of the study, the supplement and placebo are divided and numbered in containers of the same shape.The statistical consultant determines the random sequence and enters the participants into the study and assigns the participants to the intervention groups. The study participants and the researcher are blinded, and a third person outside the study, who is not aware, specifies the codes a and b

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Facility of Nutrition, Razi Blv, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7153675500

Approval date
2023-07-29, 1402/05/07

Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1402.057

Health conditions studied

1

Description of health condition studied
Ulcerative Colitis Inflammation

ICD-10 code
K51

ICD-10 code description
Ulcerative colitis

Primary outcomes

1

Description
Changes in gene Sirt1 expression

Timepoint
At the beginning of the study and 3 months later (the end of the study)

Method of measurement
Real time PCR

Secondary outcomes

1

Description
Life quality score
Timepoint
At the beginning of the study and 3 months later (the end of the study)
Method of measurement
IBDQ9 questionnaire

Intervention groups

1

Description
Intervention group: Sodium Butyrate 600 mg/day
Category
Treatment - Drugs

2

Description
Control group: Starch 600 mg/day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
Bagher Lankarani
Street address
Karimkhan Zand blv, Faghihhi hospital, Shiraz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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
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Person responsible for updating data

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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
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available