

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		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	
Scientific title		Placebo	
Effect of Butyrate on anti inflammatory genes Sirt1 and Pgc1alpha and apoptosis gene Bax and Bcl2 in Ulcerative colitis patients		Used	
Public title		Assignment	
Investigating the effect of Butyrate on inflammatory genes and apoptosis in Ulcerative colitis		Factorial	
Purpose		Other design features	
Treatment			
Inclusion/Exclusion criteria		Secondary Ids	
Inclusion criteria:		empty	
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.		Ethics committees	
Exclusion criteria:		<u>1</u>	
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		Ethics committee	
Age		Name of ethics committee	
From 18 years old to 60 years old		Ethics Committee of Shiraz University of Medical Sciences	
Gender		Street address	
Both		Facility of Nutrition, Razi Blv, Shiraz, Iran	
Phase		City	
3		Shiraz	
Groups that have been masked		Province	
- Participant - Investigator		Fars	
Sample size		Postal code	
Target sample size: 30		7153675500	
Randomization (investigator's opinion)		Approval date	
Randomized		2023-07-29, 1402/05/07	
Randomization description		Ethics committee reference number	
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.		IR.SUMS.SCHEANUT.REC.1402.057	
Blinding (investigator's opinion)		Health conditions studied	
Double blinded		<u>1</u>	
Blinding description		Description of health condition studied	
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		Ulcerative Colitis Inflammation	
		ICD-10 code	
		K51	
		ICD-10 code description	
		Ulcerative colitis	
		Primary outcomes	
		<u>1</u>	
		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, Faghihi 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

Elham Shafiee

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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

Full name of responsible person

Mohammad Vatanpour

Position

Master student

Latest degree

Bachelor

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

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