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Efficacy of sodium butyrate in inducing remission in patients with mild-to-moderate ulcerative colitis

Submission date
26/01/2025

Recruitment status
No longer recruiting

Registration date
06/02/2025

Overall study status
Completed

Last Edited
04/02/2025

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of microencapsulated sodium butyrate (MSB) as an additional therapy for inducing remission in patients with mild-to-moderate ulcerative colitis (UC).

Who can participate?
Eligible participants include mild-to-moderate UC patients (defined by a Total Mayo Score between 3-10 points), aged 18-65 years, with disease confirmed through endoscopic and histological examinations based on guidelines from the Polish Society of Gastroenterology and the European Crohn's and Colitis Organisation at least one year before the study.

What does the study involve?
Participants will be divided into two groups: one group will receive 300 mg of microencapsulated sodium butyrate (MSB) twice daily for 8 weeks, while the other group will receive 300 mg of rice starch capsules twice daily as a placebo. During the first visit and the second visit 8 weeks later, stool and blood samples will be collected to measure butyric acid [C4] concentration in stool, fecal calprotectin, C-reactive protein, erythrocyte sedimentation rate [ESR], hemoglobin [Hb], ferritin, albumin, total protein, and vitamin D3 and flexible sigmoidoscopy will be performed to access for endoscopic improvement.

What are the possible benefits and risks of participating?
Potential benefits of the study include alleviation of ulcerative colitis symptoms. To date, no side effects of sodium butyrate use have been reported.

Where is the study run from?
The study is being conducted at the Clinic of Gastroenterology and Internal Medicine, National Medical Institute, Ministry of Internal Affairs and Administration (PIM MSWiA), Poland

When is the study starting and how long is it expected to run for?
January 2020 to April 2023

Who is funding the study?
1. The Clinic of Gastroenterology and Internal Medicine, National Medical Institute, Ministry of Internal Affairs and Administration (PIM MSWiA), Poland
2. Sodium butyrate and placebo will be provided by the manufacturer, Polpharma, Poland

Who is the main contact?
Katarzyna Karłowicz, karlowiczkatarzyna@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Efficacy of microencapsulated sodium butyrate as an add-on therapy in inducing remission in patients with mild-to-moderate ulcerative colitis: Results from a multi-center, double-blind, randomized, placebo-controlled study

Acronym
CAPSULA

Study objectives
Microencapsulated sodium butyrate is effective as an add-on therapy for patients with mild-to-moderate ulcerative colitis.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 04/03/2020, The Bioethics Committee of the National Medical Institute of the Ministry of Internal Affairs and Administration (Woloska 137 Str., Warsaw, 02-507, Poland; +48477221552; komisja.etyki@cskmswia.gov.pl), ref: 35/2020

Study design
Multi-center double-blind randomized placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Therapy for mild to moderate ulcerative colitis

Interventions
The study include patients with mild-to-moderate ulcerative colitis, defined by a Total Mayo Score (TMS) between 3 and 10 points. Participants are aged 18 -65 years, with disease confirmed through endoscopic and histological examinations based on guidelines from the Polish Society of Gastroenterology and the European Crohn's and Colitis Organisation at least one year before the study. Eligible patients will be randomly assigned to either the intervention or placebo group in a 1:1 ratio using block randomization and a random number generator. The intervention group will receive 300 mg of microencapsulated sodium butyrate (MSB) twice daily for 8 weeks, the control group will receive 300 mg of rice starch capsules twice daily as a placebo. Stool and blood samples will be collected, and flexible sigmoidoscopy will be performed at baseline and after 8 weeks.

Intervention Type
Supplement

Primary outcome(s)
1. Clinical improvement is measured using TMS reduction (≥ 3 points) at week 8
2. Clinical remission is measured using TMS (≤ 2), stool frequency subscore (≤ 1), rectal bleeding subscore (0), endoscopic subscore (≤ 1 without friability) at at week 8
3. Endoscopic improvement is measured using one-degree reduction in endoscopic score at at week 8
4. Endoscopic remission is measured using Mayo score (0) at at week 8
5. Biochemical remission is measured using fecal calprotectin (≤ 250 µg/g) at at week 8

Key secondary outcome(s))
1. Butyric acid (C4) concentration in stool is measured using mass spectrometry at 8 weeks after enrollment
2. Fecal calprotectin is measured using immunochemiluminescence technique at 8 weeks after enrollment
3. C-reactive protein is measured using immunoturbidimetry (IT) at 8 weeks after enrollment
4. Erythrocyte sedimentation rate (ESR) is measured using capillary photometric-kinetic technique at 8 weeks after enrollment
5. Hemoglobin (Hb) is measured using photometric method at 8 weeks after enrollment
6. Ferritin is measured using immunoturbidimetry (IT) at 8 weeks after enrollment

7. Albumin is measured using colorimetric measurements at 8 weeks after enrollment
8. Total protein is measured using colorimetric measurements at 8 weeks after enrollment
9. Vitamin D3 is measured using chemiluminescence technique at 8 weeks after enrollment

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Age: 18–65 years.
2. Ulcerative colitis (UC) confirmed through endoscopic and histological examinations based on guidelines from the Polish Society of Gastroenterology and the European Crohn's and Colitis Organisation at least one year before the study.
3. Mild-to-moderate ulcerative colitis (defined by a Total Mayo Score between 3-10 points).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
98

Key exclusion criteria
1. Age >65 years or <18 years
2. UC limited to the rectum (proctitis - E1 in the Montreal classification)
3. Recent escalation of treatment or addition of another therapy within 24 weeks before the study,
4. Use of antibiotics, pro-/pre-/synbiotics, SCFAs, or other supplements within 12 weeks before qualification and/or during the study
5. Significant changes in diet and lifestyle
6. Diagnosis of COVID-19 during or within 8 weeks before the study
7. Other gastrointestinal diseases
8. History of colostomy or cancer

9. Hospitalization during the study
10. Pregnancy or lactation.
11. Reluctance to participate.

Date of first enrolment
01/04/2021

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
Poland

Study participating centre
Department of Gastroenterology and Internal Medicine, National Medical Institute of the Ministry of the Interior and Administration, Warsaw, Poland
Woloska 137 st.
Warsaw
Poland
02-507

Study participating centre
Department of Digestive Tract Diseases, Medical University of Lodz
Kopcińskiego 22 st.
Lodz
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90-153

Sponsor information

Organisation
Ministry of Interior and Administration

ROR
https://ror.org/03c86nx70

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Clinic of Gastroenterology and Internal Medicine, National Medical Institute, Ministry of Interior and Administration

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Katarzyna Karłowicz (karlowiczkatarzyna@gmail.com)
1. The type of data that will be shared: The study results and patient data, such as age, type of treatment, and anonymized information, will be shared.
2. Timing for availability: The data is already available.
3. Whether consent from participants was required and obtained: Consent was required and obtained.
4. Comments on data anonymization: The data has been anonymized.
5. Any ethical or legal restrictions: Approval from the bioethics committee has been obtained

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Polish		04/02/2025	No	Yes