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The effect of sodium butyrate on abdominal symptoms and carbohydrate metabolism in patients with type 2 diabetes

Submission date
08/01/2025

Recruitment status
No longer recruiting

Registration date
31/01/2025

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study aims to determine whether sodium butyrate supplementation affects carbohydrate metabolism and the severity of abdominal symptoms in patients diagnosed with type 2 diabetes.

Who can participate?
Eligible participants include type 2 diabetes patients who report gastrointestinal symptoms (meeting the Rome V criteria for the diagnosis of irritable bowel syndrome), such as abdominal pain, bloating, diarrhea, or constipation.

What does the study involve?
Participants will be divided into two groups: one group will receive 1.5 g of sodium butyrate daily, while the other group will receive a placebo. During the first visit and the second visit, 12 weeks later, blood samples will be collected to measure glucose, insulin, and glycated hemoglobin levels, and a hydrogen breath test will be performed to assess for SIBO.

What are the possible benefits and risks of participating?
Potential benefits of the study include alleviation of irritable bowel syndrome symptoms and improved carbohydrate metabolism control. 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 2021 to August 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, Bioton, Poland

Who is the main contact?
Paulina Panufnik, paulina.panufnik@cskmswia.gov.pl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of microencapsulated sodium butyrate on abdominal symptoms and carbohydrate metabolism in patients with type 2 diabetes: a randomized placebo-controlled trial

Study objectives
Sodium butyrate supplementation reduces the severity of gastrointestinal symptoms and improves carbohydrate metabolism.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/04/2021, The Bioethics Committee of the National Medical Institute of the Ministry of Internal Affairs and Administration (Woloska 137, Warsaw, 02-507, Poland; +48477221552; komisja.etyki@cskmswia.gov.pl), ref: 55/2021

Study design
Single-centre interventional double-blinded, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Treatment of gastrointestinal symptoms and improvement of carbohydrate metabolism in patients with type 2 diabetes.

Interventions
The study will include patients with type 2 diabetes who meet the Rome IV criteria for the diagnosis of irritable bowel syndrome (IBS). Participants will be randomized, using an application, into two groups: one receiving 1.5 g of sodium butyrate daily for 12 weeks and the other receiving a placebo. During two visits, at weeks 0 and 12, patients will undergo laboratory tests, a lactulose hydrogen breath test to diagnose SIBO, and will complete a questionnaire assessing the severity of gastrointestinal symptoms.

Intervention Type
Supplement

Primary outcome measure
1. Changes in carbohydrate metabolism will be measured by assessing glycated hemoglobin (HbA1c) levels and calculating the HOMA-IR index at the start of the study and after the 12-week intervention.
2. Changes in the severity of gastrointestinal symptoms will be evaluated using a gastrointestinal symptom severity questionnaire, completed by participants at the start of the study and after the 12-week intervention.

Secondary outcome measures

1. The presence of small intestinal bacterial overgrowth (SIBO) in patients will be assessed through a hydrogen breath test conducted at the start of the study and after the 12-week intervention
2. Fasting insulin levels in the blood of participants were measured using venous blood samples at the beginning of the study and after the 12-week intervention
3. Fasting glucose levels in the blood of participants were measured using venous blood samples at the beginning of the study and after the 12-week intervention

Overall study start date
02/01/2021

Completion date
03/08/2023

Eligibility

Key inclusion criteria
1. Age: 18–80 years.
2. Diagnosed type 2 diabetes with no modifications to treatment for at least 3 months.
3. Meeting the Rome IV criteria for the diagnosis of irritable bowel syndrome (IBS).

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
60

Total final enrolment
52

Key exclusion criteria
1. Age > 80 years or <18
2. Any changes in treatment within 3 months before qualification and/or during the study
3. Dietary interventions 4 weeks before qualification and/or during the study
4. Use of antibiotics 4 weeks before qualification and/or during the study
5. Use of prokinetics, antidiarrheal drugs, probiotics, sodium butyrate, proton pump inhibitors or H2 receptor blockers 14 days before qualification and/or during the study
6. Pregnancy or breastfeeding

7. Lactulose intolerance
8. Diagnosis of galactosemia

Date of first enrolment
01/10/2022

Date of final enrolment
01/07/2023

Locations

Countries of recruitment
Poland

Study participating centre
Clinic of Gastroenterology and Internal Medicine, National Medical Institute, Ministry of Internal Affairs and Administration
Woloska 137 st.
Warsaw
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02-507

Sponsor information

Organisation
Ministry of Interior and Administration

Sponsor details
Clinic of Gastroenterology and Internal Medicine, National Medical Institute, Ministry of Interior and Administration
Woloska 137 st.
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Sponsor type
Hospital/treatment centre

Website
https://www.gov.pl/web/cskmswia/klinika-chorob-wewnetrznych-i-gastroenterologii

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Paulina Panufnik (paulina.panufnik@cskmswia.gov.pl)

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