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Study on the impact of methylcellulose and a special carbohydrate on bowel gas in people with IBS and constipation

Submission date 17/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/04/2025	**Overall study status** Ongoing	
Last Edited 03/07/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Increasing fibre intake provides numerous health benefits, including reducing obesity, type II diabetes, and colon cancer. However, many individuals with irritable bowel syndrome (IBS) avoid high-fibre foods due to the discomfort and gas they can cause. One particular group of fibres, known as FODMAPs, consists of carbohydrates that humans cannot digest. These carbohydrates pass into the colon, where they are fermented by bacteria, producing gas. Inulin, a common dietary FODMAP found in bread and flour, can cause the colon to swell with gas a few hours after ingestion, which can be measured using MRI. This swelling may lead to symptoms of bloating and abdominal discomfort. Methylcellulose (MC) is an inexpensive food additive, approved as safe, and widely used by the food industry as a thickener and emulsifier. This study aims to determine if adding MC to inulin can reduce the amount of gas accumulating in the colon and, consequently, alleviate IBS symptoms. MC also acts as a mild laxative, softening stool and improving constipation. It is hypothesized that repeated consumption of inulin will, over time, alter the colonic bacteria, enabling them to use inulin more efficiently and produce less gas.

Who can participate?
Adult patients with IBS with constipation

What does the study involve?
To test these hypotheses, this study will compare the effects of MC and a placebo (maltodextrin, a readily absorbed carbohydrate) on colonic gas induced by inulin. The gas will be measured using MRI both before and after three weeks of regular inulin consumption combined with either MC or placebo. Additionally, the study will measure bowel transit time using marker pills visible on MRI scans and assess whether three weeks of inulin consumption will alter the stool microbiota and the breakdown of inulin.

What are the possible benefits and risks of participating?
The study team cannot promise that participation in the study will help, but the information generated from this study may help with future research to develop dietary supplements that would be helpful to people with IBS-C.

MC is a widely used food ingredient and approved as safe to consume.
MRI scans are noisy, and earplugs will be provided.
MRI scans use radio waves and are entirely safe following our standard MRI safety questionnaire.
Participants with tattoos may feel a burning sensation during their scan.
The scans are not intended for diagnostic purposes, so it is unlikely that any abnormalities will be detected. However, if something unusual is found, a radiologist will review the scans, and participants will be asked for their consent to allow the study team to contact their GP.
Inulin may produce gas and bloating with abdominal discomfort. The dose will be adjusted if necessary.
Although all communications are kept confidential, if any information is disclosed that is perceived to put the individual or others at risk, it may be necessary to report this to the appropriate persons.

Where is the study run from?
Sir Peter Mansfield Imaging Centre, University Park Nottingham, UK

When is the study starting and how long is it expected to run for?
September 2024 to July 2026

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Robin Spiller, robin.spiller@nottingham.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
349409

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
25001

Study information

Scientific Title
A randomised, placebo-controlled cross-over study of the effect of chronic feeding of methylcellulose and inulin on inulin fermentation in people with IBS-C

Acronym
TEMPO

Study objectives
1. Combining inulin and methylcellulose will reduce colonic gas in IBS patients with constipation after ingestion of inulin
2. Chronic feeding of inulin with or without methylcellulose will reduce colonic gas after inulin ingestion

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/03/2025, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8029; berkshireb.rec@hra.nhs.uk), ref: 25/SC/0079

Study design
Single-centre two-way randomized controlled cross-over study

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
Interventions: study participants will be given two food interventions in a randomised order:
1. A firm gel containing inulin and methylcellulose
2. A liquid containing inulin and maltodextrin (placebo).
They will be prepared in the food production facility at the University of Nottingham and stored in the fridge at 4°C and then in the participants' fridges.

All interventions will be prepared to the same concentration of inulin and intervention (methylcellulose) or placebo (maltodextrin), which is based on a volume of 375 ml water with either;
1. 15 g inulin + 15 g methylcellulose in a pot providing a final firm texture after heating
2. 15 g inulin + 15 g maltodextrin in a pot for a final drinkable texture

This is a single-centre, two-way, cross-over study in people with IBS and constipation who will receive either inulin plus maltodextrin (placebo) or inulin plus methylcellulose both given at a dose of 5 g three times daily for 3 weeks. MRI assessment will be performed using a 3 Tesla (3T) whole-body MRI system (Philips Achieva) scanner of mechanistic endpoints at baseline and after 3 weeks of the intervention. The two studies are to be separated by a 4-week washout period.

Intervention Type
Supplement

Primary outcome measure
Colonic gas volume measured by magnetic resonance imaging (MRI) at baseline and after 3 weeks

Secondary outcome measures
1. Whole gut transit measured from the position of MRI markers 24 hours post-ingestion
2. Small bowel water measured using MRI, allowing calculation of the AUC 0-6 hours post inulin ingestion
3. Breath hydrogen measured using MRI, allowing calculation of the AUC 0-6 hours post inulin ingestion
4. Faecal microbiota measured using shotgun metagenomic sequencing at baseline and after 1 and 3 weeks

Overall study start date
01/09/2024

Completion date
01/07/2026

Eligibility

Key inclusion criteria
Meet Rome IV criteria for IBS with constipation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
22

Key exclusion criteria
1. Pregnancy, lactating, or planning pregnancy during the course of the investigation declared by the candidate
2. History declared by the candidate of pre-existing gastrointestinal disorder other than IBS-C that may affect bowel function including but not limited to:
3. Inflammatory Bowel Disease
4. Coeliac Disease
5. Pancreatitis
6. Gallstone disease (biliary colic, cholecystitis; asymptomatic presence of gallstones permitted)
7. Complicated diverticulitis (asymptomatic presence of diverticula permitted)
8. Cancer of the gastrointestinal tract
9. Gastroparesis
10. Other functional gastrointestinal disorders will be permitted as they frequently co-exist with IBS.
11. Reported history of previous resection of the oesophagus, stomach, or intestine (excluding appendix)
12. Intestinal stoma
13. Have contraindications for MRI scanning i.e. metallic implants, pacemakers, history of metallic foreign body in eye(s) and penetrating eye injury
14. Unable to lie flat and relatively still for less than 5 minutes
15. Any medical condition potentially compromising participation in the study e.g., diabetes

mellitus, respiratory disease limiting ability to use breath hydrogen analyser, known intolerance to one of the test substances
16. Has a body mass index (BMI) value less than 18.5 or greater than 35
17. Will not agree to follow dietary and lifestyle restrictions required
18. Unable to stop opiate use or planning to change medication which might alter GI motility.
19. Mebeverine, calcium channel antagonists, selective serotonin reuptake inhibitors, low-dose tricyclic antidepressants, antihistamines, and oral contraceptive pills will be recorded in the CRF but will not be an exclusion criteria provided no change in dosage is planned during the study period.
20. Participants who have taken antibiotics or probiotics within the last 4 weeks
21. Poor understanding of the English language
22. Participation in night shift work the week prior to the study day. Night work is defined as working between midnight and 6.00 AM

Date of first enrolment
01/05/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sir Peter Mansfield Imaging Centre
University Park
Nottingham
United Kingdom
NG72UH

Sponsor information

Organisation
University of Nottingham

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Peer reviewed journals and presentation at conferences

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan

The datasets generated will be available upon request from Prof. Robin Spiller (robin.spiller@nottingham.ac.uk). The consent form includes confirmation for sending anonymised data to other researchers. All data are anonymised. There are no further ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	17/02/2025	24/03/2025	No	No