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A research study looking at faecal transplant as a treatment for ulcerative colitis, and the best way to use it in patients with the condition

Submission date 31/08/2017	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/09/2017	**Overall study status** Stopped	
Last Edited 27/01/2026	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
The human body contains vastly more bacteria (bugs) than human cells and it is becoming increasingly clear that these bacteria have important and previously unrecognised effects on the body. The majority of these bacteria reside in the colon and it is now known that the bacterial population (microbiome) in patients with ulcerative colitis (UC) is different from that of healthy people. Over the past 10 years doctors and patients from many countries have attempted to change the microbiome in UC using FMT (faecal microbiota transplant (transfer of faeces from a healthy individual to a person with disease)), and their attempts have suggested that this may be an effective treatment. However there has never been a study with enough patients to truly assess the effectiveness of this treatment. We are initially conducting a small “pilot” study to compare the two available ways of giving FMT (into the stomach via a naso-gastric tube or the directly into the colon). Participants will receive either FMT via naso-gastric (NG) route or colonic route. Stool and urine samples will be collected for genetic testing and microbe studies. These two routes will be compared to determine the effectiveness and acceptability of the two possible ways of giving FMT. The aim of this study is to look for signals that the methods are working in order to go forward with either method of FMT into the larger study.

Who can participate?
Adults aged 16-70 years old who have confirmed ulcerative colitis.

What does the study involve?
Participants are randomly allocated to one of two FMT routes. Those in the first group receive the naso-gastric (NG) route and those in the second group undergo the colon route. All participants are monitored for six hours after the procedure. Participants are followed up eight weeks after the procedure to assess their disease activity and provide samples for testing the amount of microbome. They also participate in interviews 12 weeks after to assess their quality of life.

What are the possible benefits and risks of participating?
The main benefit will be that information gained from the trial will help better understand the

possibility of using FMT as a novel therapy for UC. It is possible that this treatment will make UC better. The results of this pilot study will help us determine if we should proceed to a larger study of FMT for the treatment of UC.

Where is the study run from?
1. Queen Elizabeth Hospital Birmingham (UK)
2. St Mark's Hospital (UK)
3. Glasgow Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
August 2015 to July 2022

Who is funding the study?
National Institute for Health Research Efficacy and Mechanism Evaluation (EME) Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2015-005753-12

Integrated Research Application System (IRAS)
170888

Protocol serial number
CPMS 35522, IRAS 170888

Study information

Scientific Title
A prospective, open-label, randomised pilot study to assess two possible routes of Faecal Microbiota Transplant (FMT) delivery in patients with ulcerative colitis.

Acronym
STOP-Colitis Pilot Trial

Study objectives
The aim of this study is to assess the effectiveness and acceptability of the two routes, NG (naso-gastric) or COLON of FMT delivery, and to determine whether FMT by either NG or COLON is suitable to take forward to a double-blinded randomised controlled trial (RCT) to investigate the efficacy of FMT (vs. placebo) in achieving and maintaining remission in patients with active ulcerative colitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham REC 2- East Midlands, 30/06/2017, ref: 17/EM/0274

Study design
Randomized; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Gastroenterology, Primary sub-specialty: Gastroenterology; UKCRC code/ Disease: Oral and Gastrointestinal/ Other diseases of the digestive system

Interventions
Following confirmation of eligibility criteria and written informed consent having been obtained for screening, in accordance with Good Clinical Practice standards, patients are provided IBD diares and stool kits for stool sample to be returned and tested for Clostridium difficile. Once, the C.diff has been confirmed negative, appointments arearranged for patients to attend clinic for randomisation and delivery of the first FMT dose. Participants are instructed to take standard bowel preparation the day before the clinic appointment. Participants also take part in a semi-structured interview with a qualitative researcher prior to randomisation.

On day of randomisation, eligibility is re-confirmed and participants are provided written informed consent for trial entry. Participants complete all baseline assessments, and are randomised to one of two FMT routes: Naso-gastric (NG) route or Colonic route using a computer-generated program at the Birmingham Clinical Trials Units (BCTU). After randomisation all participants have a colonoscopy to assess disease according to the MAYO Score and mucosal biopsies are collected.

NG route:
Participants are pre-treated with a proton pump inhibitor (lansoprazole) and a prokinetic agent (domperidone) at least 30 minutes before each FMT infusion to reduce gastric secretion and prevent the risk of regurgitation respectively. NG tubes are passed and checked for correct position as per the local Site protocol for NG tube insertion. Following colonoscopy, 50ml thawed FMT treatment are infused as per the STOP-Colitis protocol. In this NG route, 50ml FMT are delivered each day over four consecutive days. Patients in the NG arm then have a further four days treatment beginning at the week four visit following a fast from midnight. Participants receive single dose loperamide after each FMT delivery. Participants who complete the treatment according to the protocol receive in total, 240g FMT.

Colon route:
Participants undergo standard colonoscopy and FMT using a thawed 250ml FMT aliquot in normal saline and 10% glycerol containing 150g of donor stool. Of the 250ml suspension, 125ml are sprayed into the caecum via a spray catheter at colonoscopy with the remaining 125ml sprayed directly onto the rest of the colon (after samples obtained). Thereafter, weekly faecal enemas are administered containing 30g donor stool made up to 100ml with normal saline in 10% glycerol up to week seven. Patients receive a single dose of loperamide after each FMT delivery. Patients who complete the treatment according to the protocol receive in total 360g FMT.

After each FMT delivery, all participants are monitored for up to six hours in the Clinical Research Facility. Medically trained personnel examine participants and in the unlikely event of significant adverse event(s) in relation to colonoscopy or the development of systemic symptoms such as vomiting, pyrexia or hypotension, clinical investigators will consider admitting patients overnight.

At week 8 participants are followed-up to undergo a flexible sigmoidoscopy to assess (a reduction in) disease activity according to the MAYO score and samples for mucosal histological assessments are taken for later mucosal microbiome assessment.

At week 12, which is the last follow-up visit, participants attend for final assessments and clinical review. After this visit, participants take part in a follow-up semi-structured qualitative research interview as soon as possible after this week 12 assessment in a non-clinical setting.

Intervention Type
Other

Primary outcome(s)
1. Clinical response (primary measure of efficacy) defined as ≥3 point reduction in the full Mayo score from randomisation to week 8, and 30% reduction from randomisation and at least 1 point reduction of rectal bleeding subscore or an absolute rectal bleeding subscore of 0 or 1
2. Time to clinical response where clinical response is defined as ≥2 point reduction in partial Mayo
3. Clinical remission is measured using the full Mayo score of ≤2, with no subscore >1 at week 8
4. Participant's weight is measured using scales at week 8 and week 12
5. Quality of Life (QoL) is meaured using generic Short-Form 36 (SF-36) and the disease specific Inflammatory Bowel Disease Questionnaire (IBDQ) at week 8 and week 12

Key secondary outcome(s))

1. Faecal calprotectin is measured from sample collected at randomisation, weeks 2, 4, 6, 8 & 12
2. Measures of microbiome (faecal and mucosal) is measured from sample collected at randomisation, weeks 4, 6, & 8
3. Mucosal healing is measured from biopsies at randomisation and week 8
4. Urinary metabolome (SCFA) is measured from sample collected at randomisation, weeks 8 & 12
5. CRP is measured from sample collected at randomisation, weeks 2, 4, 6, 8 & 12
6. Association between the donor's dietary profile and microbiome
7. Time from stool donation to treatment

Completion date
31/07/2022

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Clinically confirmed ulcerative colitis (UC) for at least ≥12 weeks prior to the screening visit
2. Aged 16-70 years
3. Partial Mayo score of ≥4 and ≤8 despite stable 5ASA+/- thiopurine, methotrexate or no treatment
4. Rectal bleeding subscore of ≥1 on the partial Mayo
5. Written, signed informed consent to the study
6. Males or females

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
70 years

Sex
All

Total final enrolment
30

Key exclusion criteria

Donors:
1. GI history of:
1.1. Inflammatory bowel disease
1.2. Irritable bowel syndrome, idiopathic chronic constipation or chronic diarrhoea
1.3. Gastrointestinal malignancy or known polyposis
1.4. Celiac disease
1.5. Congenital or chronic liver disease
1.6. Per rectal bleeding
1.7. Major gastrointestinal surgery (eg gastric bypass)
2. Autoimmune history of systemic autoimmunity including:
2.1. Connective tissue disease
2.2. Thyroid disease
2.3. Inflammatory arthritis
2.4. Psoriasis
2.5. Alopecia
3. Atopic disease inc:
3.1. Asthma
3.2. Atopic dermatitis
3.3. Eczema
3.4. Eosinophilic disorders of the gastrointestinal tract
4. Chronic pain history of:
4.1. Chronic fatigue syndrome
4.2. Fibromyalgia
5. Cardiovascular history of a cardiovasular or metabolic syndrome including:
5.1. Diabetes (type 1 or type 2)
5.2. High blood pressure
5.3. High cholesterol
5.4. High fasting glucose
5.5. Heart disease (eg atherosclerosis, myocardial infarction, congestive heart failure)
6. Neurological history of neurological conditions including:
6.1. Multiple Sclerosis
6.2. Parkinson’s disease
6.3. Alzheimer’s disease or dementia disorders
7. Immunosuppression history of any major immunosuppressive mechanisms including:
7.1. Calcineurin inhibitors
7.2. Exogenous glucocorticoids
7.3. Biological agents
7.4. Anti-TNF factors
7.5. Systemic chemotherapeutic anti-neoplastic agents
7.6. Transplantation (eg solid organ, bone marrow, cornea etc)
8. Mental health and well being history of having been diagnosed by a clinician with any of the following:
8.1. Depression
8.2. Bipolar disorder
8.3. Schizophrenia or delusional disorder
8.4. Eating disorder (eg anorexia and / or bulimia)
9. Infectious diseases:
9.1. Known to have HIV, HBV and/or HCV infection
9.2. Known to have been exposed to HIV, HBV and/or HCV in the preceding 12 months
9.3. Risk of Creutzfeldt-Jakob disease (CJD) or variant CJD
9.4. Originate from or share sexual partners or have a parent who originates from areas with high-incidence Human T-cell

10. Lymphotropic Virus eg Caribbean, Japan, South America and Africa.
10.1. Positive microbiology testing for any of the pathogens described donor testing schedule
11. High risk activities for bloodborne infections Engaged in any known high risk activities for blood-borne infections, including:
11.1. Sexual contact with an individual with known or suspected HIV, AIDS and/or hepatitis
11.2. Sexual contact with a man who has had sex with another man
11.3. Sex for drugs or money (both receiving and/or paying)
11.4. Use of illicit drugs including IV, oral or inhaled
11.5. Tattoo or body piercing in the preceding 6 months
12. Medications, probioics and vaccinations
12.1. History of proton pump inhibitor use
12.2. History of antibiotics within the preceding 3 months
12.3. History of receiving growth hormone, insulin from cows or cloting factor concentrates
12.4. History of receiving an experimental medicine or experimental vaccine
12.5. History of VSL3 probiotic food supplement or Mutaflor probiotic use
12.6. History of receiving a live vaccination within the preceding one month
13. Dietary, social and travel history
13.1. Participation in a strict vegan diet
13.2. Work or volunteering activities in which the donor comes into contact with animal or human tissues
13.3. Any previous tobacco use
13.4. Travelled outside Europe, North America or Australasia in the preceding 3 months
14. Family hisotry:
14.1. History of a first degree relative diagnosed with colon cancer under the age of 55
14.2. History of a first degree relative having inflammatory bowel disease

The following are exclusion criteria which if highlighted in the donor health questionnaire must be explored in detail with the donor.
1. History of any malignancy other than gastrointestinal malignancy
2. Use of medications not listed as absolute exclusion criteria
3. Other medical conditions highlighted but not listed as an absolute exclusion criteria
4. High risk occupation e.g. microbiology technician, health care worker, sewerage worker, vet, mortuary technician etc.
5. Travel abroad in the last 3 months with associated febrile illness
6. Travel associated risk of Zika virus infection (exclude for 1 month post return from an endemic country)
7. Illness other than that involving the gastrointestinal tract in the last 2 weeks

Patients:
1. Stool positive for Clostridium difficile or infection by either PCR or ELISA
2. Positive for Hepatitis A/B/C, and/or Human Immunodeficiency Virus (HIV) infection
3.Antibiotics within last 12 weeks prior to screening visit
4.Systemic/topical steroids in the preceding 2 weeks prior to screening visit
5.Biologics in the preceding 12 weeks prior to screening visit
6.Commercial probiotics and prebiotics in the preceding 12 weeks prior to screening visit
7.On oral nutritional supplements or enteral/parenteral nutrition in the preceding 4 weeks prior screening visit
8.Pregnant or lactating. Spot urine testing will be performed at screening to rule out pregnancy in females
9.Not willing to take appropriate contraceptive measures to prevent pregnancy during trial participation.

Date of first enrolment
01/03/2018

Date of final enrolment
10/04/2019

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Birmingham
England
B15 2TH

Study participating centre
St Mark's Hospital
London North West Healthcare NHS Trust
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Study participating centre
Glasgow Royal Infirmary
NHS Greater Glasgow and Clyde
84 Castle Street
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Sponsor information

Organisation

University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2026	27/01/2026	Yes	No
Protocol article	protocol	11/11/2019	12/11/2020	Yes	No
HRA research summary			28/06/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes