

# Faecal microbiota transplantation in ulcerative colitis

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
02/07/2015	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
24/07/2015	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
09/04/2019	Digestive System	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Ulcerative colitis (UC) is a chronic, relapsing debilitating form of inflammatory bowel disease. The number of people suffering from the condition in the UK is increasing. The cause is unknown but is considered to result from the body's response to bacteria found in the large intestine in genetically susceptible individuals. Current treatment aims to dampen the immune response with daily tablets and enemas, although symptoms often return once medication is stopped. On occasion, medical treatment doesn't work and surgery to remove the large intestine is required. It has been suggested that if the bacteria present in the large intestine in UC patients were replaced with those found in healthy people then the immune damage would reverse.

Administration of healthy bacteria to repopulate the bowel (faecal bacteriotherapy, FBT) is a recommended treatment for certain bowel infections, such as *Clostridium difficile* colitis, and the therapy has been shown to be safe and work well. The first report of FBT as a treatment for UC was in 1989, with reports of patients remaining in remission for up to 25 years. Studies are however limited to small patient series with variable methodology, including route of administration and dose frequency, and a lack of standardisation. This study aims to find out the optimal conditions in which to conduct a large scale study of FBT in patients with limited UC. We want to know the optimal frequency of FMT administration by the enema route (single dose or 5 doses) in patients with inflammation limited to the rectum and sigmoid colon compared with a control group.

### Who can participate?

Patients aged at least 18 with UC.

### What does the study involve?

Participants are randomly allocated to one of three groups. Those in group 1 are given a faecal microbiota transplant (FMT) by retention enema on one occasion. Those in group 2 are given a FMT on five consecutive days. Those in group 3 act as controls and are given bowel purgatives and antibiotic preparation and do not receive FMT. Response to the treatment is measured by endoscopic assessment at 12 weeks, patient symptom scores, blood testing, tissue biopsy and measurement of tissue inflammatory cytokine levels. The faecal bacterial profile is monitored to

ensure that the transplant is durable. Donors are carefully screened for infectious diseases to minimise the risk of transmission. The results of the study will be used to plan a large scale study to establish FMT as a viable therapy in UC patients.

What are the possible benefits and risks of participating?

The benefits of participating in the trial are that patients may experience improvement in their colitis symptoms as reported in previous small studies. There is a small but theoretical risk of transmission of as yet unknown infectious disease, despite through systematic testing of donated material for known pathogens in accordance with current guidelines.

Where is the study run from?

Abertawe Bro Morgannwg University LHB (Wales)

When is the study starting and how long is it expected to run for?

September 2015 to March 2018

Who is funding the study?

NISCHR Pathway to Portfolio (Wales)

Who is the main contact?

Professor Dean Harris

## Contact information

### Type(s)

Scientific

### Contact name

Prof Dean Harris

### ORCID ID

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

# Faecal Microbiota Transplantation in Ulcerative Colitis: an Interventional randomised single blind phase II trial

## Acronym

FMTUC

## Study objectives

To estimate the magnitude of treatment response of ulcerative colitis to FMT

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Wales REC6 ethics committee, 21/09/2015, ref: 15/WA/0262

## Study design

Interventional randomised single-blind phase II trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Ulcerative colitis

## Interventions

Faecal microbiota transplant (FMT) will be administered by retention enema to patients either once only (group 1) or on five consecutive days (group 2). A third group with active disease will act as controls and receive bowel purgatives and antibiotic preparation without active administration of FMT. Randomisation to each group will be web-based.

## Intervention Type

Other

## Primary outcome(s)

1. Remission of UC (mucosal healing) at 12 weeks as assessed by sigmoidoscopy, and patients response. Will also be measured utilising the Mayo scoring system for assessment of ulcerative colitis activity at 12 weeks, with remission defined as a Mayo score  $\leq 2$  with an endoscopic Mayo score of 0.
2. Successful engraftment of donor faecal microbiota at 12 weeks as analysed by 16S sequencing

## Key secondary outcome(s)

1. Rate of recruitment of patients
2. Disease specific severity scoring after treatment
3. Histological grading of colitis severity after treatment
4. Mucosal immunological response to treatment
5. Rate of development of adverse effects of FMT

**Completion date**

30/09/2020

## Eligibility

**Key inclusion criteria**

1. Newly diagnosed histologically confirmed ulcerative colitis with inflammation limited to the rectum or rectosigmoid (within 40cm of anal verge as measured by flexible sigmoidoscope)
2. Age 18 years and above
3. Able to give full informed written consent
4. Willing to return for sequential FMT dosing and endoscopic assessment
5. Not in receipt of standard medical treatment for colitis such as steroids or 5-ASA ie treatment naive

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients without a definitive diagnosis of UC (for example diagnosis of Crohn's disease or infectious colitis)
2. Have colitis extending beyond 40cm from the anal verge
3. Have severe acute colitis (defined as greater than 6 bloodstained stools per 24 hrs with one of the following: pulse rate >90/ temperature >37.8°C/ haemoglobin <105g/L / ESR>30)
5. Abdominal tenderness on examination
6. Already commenced standard medical therapy for UC
7. Contraindication to oral bowel preparation
8. Allergy to study antibiotics
9. Age less than 18
10. Patient is within a vulnerable group
11. Are pregnant
12. Are immuno-suppressed e.g. transplant patient
13. Known communicable disease; at least 2 weeks full recovery from infectious disease e.g. chickenpox
14. Systemic autoimmunity, or atopic diseases
15. Previous prosthetic implant (for example metallic heart valve, joint replacement, ventriculoperitoneal shunt, cardiac stent)
16. Chronic pain syndromes (for example: fibromyalgia, chronic fatigue)
17. Neurologic, neuro-developmental or neurodegenerative disorders

18. Depression (requiring therapy)
19. Obesity (BMI>35)
20. Malignancy
21. Use of antibiotics for any indication within the past 3 months
22. Foreign travel to areas of enteric disease prevalence within 3 months
23. High risk sexual behaviour (examples: sexual contact with anyone with HIV/HTLV/AIDS or hepatitis B/C carrier, men who have sex with men (MSM))
24. Known exposure to HIV or hepatitis B/C
25. Current/previous use of injected drugs or intranasal cocaine
26. Tattooing, piercing, cosmetic botulinum toxin (Botox) or permanent makeup within 120 days (in line with Welsh Blood Transfusion guidelines)
27. Recent transfusion, transplant or skin graft
28. Risk factors for variant Creutzfeldt-Jakob disease e.g. blood transfusion or transplant after 1st January 1980

**Date of first enrolment**

30/09/2015

**Date of final enrolment**

31/03/2020

## Locations

**Countries of recruitment**

United Kingdom

**Study participating centre**

Abertawe Bro Morgannwg University LHB

Port Talbot

United Kingdom

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## Sponsor information

**Organisation**

Abertawe Bro Morgannwg University LHB (UK)

**ROR**

<https://ror.org/04zet5t12>

## Funder(s)

**Funder type**

**Funder Name**

NISCHR Pathway to Portfolio

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not expected to be made available

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	18/10/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes