

FERARO: A prospective, randomised placebo controlled feasibility trial of Faecal microbiota Transplant to ERadicate gastrointestinal carriage of Antibiotic Resistant Organisms

POST: Patient and Public Involvement (PPI) member of the Trial Steering Committee (TSC)

DURATION: Until December 2021

BACKGROUND: We are seeking a lay member to assist us in improving our research by offering a patient/public perspective. Contributions will involve face-to-face meetings (twice per year) at St. Thomas' Hospital in London and review of documents via email on a more regular basis.

Following an initial introductory meeting or telephone conversation, you will be involved in assessing the road research aims and plans, developing and reviewing recruitment of participants, intervention and dissemination materials, and raising and discussing any practical limitations of the proposed strategies.

Formal qualifications and/or knowledge are not required. A willingness to discuss your opinions and experiences with members of the research team as well as access to a computer and email and the ability to attend meetings at St Thomas' Hospital is the only requirement. A summary of the research study can be found at the end of this document.

RESPONSIBILITIES:

1. Attend two meetings per year as a member of the Trial Steering Committee

Meetings will be held at St. Thomas' Hospital, Westminster Bridge Road, London SE1 7EH and will last approximately 2-3 hours.

The meetings will provide a forum for the research team and external advisors to discuss the progress of the research, forthcoming work and any issues that may have arisen.

We understand that sometimes people may be unable to attend these meetings and any minutes or other relevant documentation will be circulated.

2. Home reviewing

You will be asked to review and comment on a range of documents relevant to the research such as participant information sheets, consent forms, results summaries and evidence briefs.

You will be given instructions regarding what is specifically required of the document reviewing, however it is important to remember that you have been asked to be involved because you represent the patient or lay person perspective.

Your input and feedback can ensure that the results of our study are understandable to patients, the public and get to as wide an audience as possible.

OTHER INFORMATION AND SUPPORT:

- Expenses incurred towards attending meetings (e.g. travel costs, parking, childcare costs) will be covered by the research grant.
- An honorarium will be offered for meeting attendance and home reviewing.
- Admin support will be provided by the research team (e.g. electronic and hard copies of documents, expenses forms and prepaid envelopes)
- You will be provided with a contact within the research team to answer and queries or concerns and discuss the task you are given.

Lay Summary of the Study:

What is this study about?

The human gut has trillions of bacteria (bugs) which are important to keep us healthy. In total these bugs are called the microbiota. The bugs are always evolving to beat antibiotics used to fight them (resistance). Resistance to antibiotics allows bugs to survive and spread. This is a growing and serious threat to worldwide health, and means that doctors may be limited in the types of treatments that they can offer to patients. Without effective antibiotics even simple infections could become deadly, making routine medical procedures too dangerous to perform. There is an urgent need to find new antibiotics, but this takes time and is very expensive. There is growing interest in non-antibiotic treatments like Faecal Microbiota Transplant (FMT) to deal with this problem.

FMT is the transfer of bacteria from the guts of healthy donors (taken from their poo) into the gut of a patient. The aim is to restore a healthy balance of bacteria (reducing harmful ones and increasing good ones). It is currently used to treat patients with repeated *Clostridium difficile* infection. This is an infection causing severe diarrhoea and stomach pain, normally after having antibiotics which have harmed the microbiota. FMT is very effective and safe in treating this group of patients, with success rates of over 80%. Initial research shows that it may be helpful in other conditions. Especially for excluding antibiotic resistant bacteria (ARB) found in some patients' guts.

How will this study help people?

This study will look at whether giving FMT to patients with ARB is an achievable treatment. We will see if it is both safe and acceptable to patients, without side effects. This will allow doctors to treat infections in these patients better. If the treatment works it could be rapidly brought into the NHS. This could help patients who have ARB and can't be treated with current antibiotics.

What will we do in this study?

We will involve patients and members of the public by inviting them to have a say in how the study is designed, performed and reported. 40 patients with ARB will be randomly chosen to receive FMT (swallowed as capsules). Another 40 patients will be randomly chosen to receive identical capsules without the bugs. This is known as a 'placebo'. Patients will have stool (poo) samples collected before and after FMT. These will be taken at days 9, 16, 32, 92 and 182. We will use these to see what impact the treatment has on their gut bugs. We will also see if the treatment causes any side effects like bad taste, burping, diarrhoea and infection.

If you are interested in joining this committee or would like further information, please contact Dr Simon Goldenberg 0207 188 8515 simon.goldenberg@gstt.nhs.uk

If you are applying please tell us why you would like to join and what you can bring to the committee. Please contact us by Friday 26th July 2019.