ENTERAL FEEDING OF FIBRE TO IMPROVE MICROBIOTA

Clinical Protocol, v.4.0 01-02-2023

IRAS REF: 315656

REC REF: 22/WM/0222

Full Title:

Does distal enteral feeding of fibre positively affect the microflora in the distal limb of loop ileostomy patients?

Sponsor: Lancashire Teaching Hospitals NHS Foundation Trust

[Email address]

Clinical Protocol

Version 4 – 01/02/2023

Sponsor: Lancashire Teaching Hospitals Trust

Full title: Does distal enteral feeding of fibre positively affect the microflora in the distal limb of loop ileostomy patients?

Short title: Enteral feeding of fibre to improve microbiota.

IRAS number: 315656

Background

Following surgical removal of diseased bowel, patients often require a temporary redirection of bowel contents to a stoma, to allow healing prior to re-joining of the remaining bowel at a later date. Some patients may experience complications, either during or after reversal surgery, and this may be due to changes in the 'friendly' bacteria that live in our bowels. Our previous research shows that the distal section of bowel that is non-functioning undergoes tissue-wasting and the 'friendly' bacteria that help our digestion die (Beamish et al. 2017). Our data also shows that patients with less bacteria in the distal bowel may be more likely to develop post-operative complications. This research aims to investigate ways to increase the numbers of friendly bacteria to improve the health of the distal, non-functioning, bowel by adding fibre to the nutritional supplement fed to the distal bowel for around 2 weeks prior to surgery. The aim is that this will reduce the risk of complications and possibly reduce the recovery time from bowel surgery.

Rationale

To assess whether feeding the distal bowel, through the stoma, increases the growth of friendly bacteria in the distal (defunctioned) intestine.

Objectives

To provide pilot data for a trial to see whether stoma feeding may improve the health of the intestine, and reduce post-operative complications, in a larger group of patients that undergo stoma reversal surgery. Laboratory analysis will assess the microbiota using 16S rRNA sequencing and qPCR, comparing defunctioned and functional limbs of the ileostomy. Biomolecular analysis of the tissues, to assess growth and inflammation, will be carried out using histological and flow cytometric techniques.

Eligibility Criteria

Any individual that has been identified for distal (stoma) feeding that is able to understand verbal and written English to provide informed consent.

Informed Consent

Please approach the patient either on a pre-feeding visit, or on their first visit for distal feeding. Explain that adding fibre to the Ensure™ product, used in stoma feeding, may help the growth of friendly bacteria and help the reversal surgery. Please also explain that the small section of bowel that is usually removed, and discarded, during surgery and will be taken to the labs at Lancaster University to find out whether feeding helped the bowel and bacteria to grow. Please provide the participant information sheet for them to take home and consider.

Upon the next visit, please present a consent form and be prepared to answer any questions the participant may have regarding the addition of the fibre supplement.

Feeding Protocol

Patients will be assigned to stoma feeding by the Colorectal Surgeon, which will be managed by the stoma nurses for the duration, approximately 4 weeks, of feeding. For the final 7-14 days (minimum 7 days) of feeding, 10g of soluble fibre will be added to 100ml of Ensure™ (or equivalent liquid nutrient feed) before instillation into the stoma on a daily basis. The soluble fibre will be provided in 10g portions and should be added to the newly-opened bottle of ensure and shaken to mix well.

Participant compliance with the stoma feeding should be noted, e.g. whether distal feeding was carried out every day as advised, or whether some days were missed/partially completed. A 'feeding diary' is provided for this purpose, which should be completed by the participant and handed to the stoma nurse at the end of the study. Details of other feeding should also be noted e.g. how many days on diarolyte or Ensure™ without fibre, and how many days with the fibre added. Please record/store all these details in the 'Non-Identifiable Patient Data Record', along with BMI and any history of antibiotic usage for the duration the stoma was in place.

It is expected that the fibre will be tolerated well. In the unlikely case of excessive flatulence or bloating, over and above using ensure alone, please cease addition of the fibre and inform the clinical investigator, Mr Arnab Bhowmick, on 07912 234608.

Tissue Sample Collection

During ileostomy reversal surgery, as part of the routine procedure, the surgeon will remove approximately 2 cm of the bowel from both the ends of the proximal and distal stoma. Immediately upon removal, the tissue should be placed into two separate pots of minimum essential media (provided by Lancaster University to be kept in fridge) on ice and pots labelled (by hand) whether tissue is derived from the proximal or distal limb of the stoma.

The surgical nurse is usually responsible for handling the tissue, and for notifying Lancaster University personnel to arrange collection and transport as soon as possible – please see SOP for further details.

Important:
Notify Rachael Rigby (rachael.rigby@lancaster.ac.uk) when participants are due for surgery

and please advise an approximate time for collection of tissue on day of surgery (07814 574952).

Participant tissue samples must be kept chilled at 2-5°C (on ice) for collection.

Post-surgical follow up/CRF:

Please record blood work (CRP, WBC, Albumin, etc.) and any clinical observations or complications (e.g. anastomotic leak, ileus, excessive distention/bloating or wound infection) in the 'Non-Identifiable Patient Data Record'. Patient BMI, sex, date of stoma creation, length of stay in hospital and history of antibiotic usage (name/duration) during the time stoma was in place should also be recorded. The non-identifiable data and feeding diary, completed by the patient (anonymously identified by participant number SFS00*), should be emailed to rachael.rigby@lancaster.ac.uk within 90 days post-surgery.

Definition of end of study

The end of the study will be declared following collection of 15 participant samples and completion of all analysis. This is anticipated to be 01/12/2025.