

# A low FODMAP diet for diarrhoea predominant functional gastrointestinal disorders in neuroendocrine tumour patients

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| <b>Submission date</b><br>23/11/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>11/12/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>23/04/2021       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

A low FODMAP diet is a diet low in Fermentable Oligo-, Di-, Mono-saccharides and Polyols. In basic terms, it is a diet low in foods that make extra gases in the intestines. It is a relatively new dietary approach for the management of irritable bowel syndrome (IBS) symptoms and was pioneered in Melbourne, Australia. It has been researched for a number of years and has been shown to be effective at treating gut symptoms such as bloating, wind, abdominal pain and diarrhoea. The diet involves restricting various foods including those grains, fruits and vegetables that are high in FODMAPs, which may reduce diarrhoea related to functional gastrointestinal disorders in patients with neuroendocrine tumours (NET). The aim of this study is to find out whether a low FODMAP diet is useful for controlling functional gastrointestinal disorders in NET patients.

### Who can participate?

NET patients with diarrhoea-predominant functional gastrointestinal disorders.

### What does the study involve?

Participants are randomly allocated to either consume a low FODMAP diet for 4 weeks, or to be given a Nutrition in NETs booklet.

### What are the possible benefits and risks of participating?

The potential benefits are more likely in the low FODMAP diet group. Since previous studies show a high success rate (nearly 70%) in controlling diarrhoea-predominant IBS, it is likely that a high proportion of NET patients will benefit from following the diet. This may, as predicted, lead to improved quality of life and at least weight stability. Patients who have been seen already in the NET unit have reported weight gain, reduced diarrhoea and improved quality of life after implementation of the low FODMAP diet. Some patients may improve on the advice within the Nutrition in NETs booklet, but only if they did not already learn to exclude the foods which can lead to the diarrhoea and associated gas production beforehand. After the 4-week study, if the participant had not improved on that advice, they are welcome to liaise with the dietitian to try the low FODMAP diet. In the low FODMAP group there is a risk that the patient could lose

weight, although this is unlikely because the predicted decrease in diarrhoea from following the diet should aid nutrient absorption and therefore help to maintain weight. The diet only runs for 4 weeks rather than 8 weeks as it has been found in other studies that improvements are normally seen quicker with patients with diarrhoea-predominant functional gastrointestinal disorders. The low FODMAP diet could also be an inconvenience as it takes time to learn what foods are allowed and what meals they can cook. Costs of ready made labelled gluten-free items can cost more than standard products but there are plenty of foods which are naturally low in FODMAPs without costing more, and the booklets list these and also some recipes to make items at home. There are no perceived risks from being in the booklet group, although it may be slightly irritating for a patient if they wanted to do the low FODMAP diet without starting with the standard care first. The patient may have already received this booklet before and not seen a dietitian so they would get to do this on the study. If the patient would like further help controlling their diarrhoea after the 4-week period they are welcome to ask for a referral to the dietitian to discuss the low FODMAP diet as any patient would do normally outside the study. Time taken to be in the study and to fill out forms may also be a inconvenience. Procedures will be done quickly within recommended timeframes without risking bias by pressurising responses of participants.

Where is the study run from?  
The Royal Free Hospital (UK)

When is the study starting and how long is it expected to run for?  
January 2014 to December 2018

Who is funding the study?  
The Royal Free Hospital (UK)

Who is the main contact?  
Tara Whyand

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Miss Tara Whyand

**ORCID ID**  
<https://orcid.org/0000-0003-3451-8441>

**Contact details**  
The Royal Free Hospital  
London  
United Kingdom  
NW3 2QG

## Additional identifiers

## Study information

## **Scientific Title**

A low FODMAP diet for diarrhoea predominant functional gastrointestinal disorders in pancreatic and mid-gut neuroendocrine tumour patients

## **Study objectives**

Primary research question:

Is a low FODMAP diet useful in controlling functional gastrointestinal disorder problems in mid-gut and pancreatic NET patients?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee London - Surrey Borders, 19/12/2013, REC ref: 13/LO/1506

## **Primary study design**

Interventional

## **Study design**

Single-center randomised controlled trial

## **Study type(s)**

Quality of life

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

Diarrhoea predominant functional gastrointestinal disorders in pancreatic and mid gut neuroendocrine tumour patients

## **Interventions**

Low FODMAP diet group: complete a 4-week dietary intervention

Standard treatment group: are given a Nutrition in NETs booklet only

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Frequency of diarrhoea, measured using the Bristol Stool Chart and the NET21 quality of life questionnaire at baseline and 4 weeks

## **Key secondary outcome(s)**

1. Weight, measured using weighing scales

2. Quality of life, measured by the QLQ C-30 and NET21 Quality of life questionnaires

All outcomes are measured at baseline and 4 weeks.

## **Completion date**

31/12/2018

## **Eligibility**

### **Key inclusion criteria**

Adult patients who have diarrhoea predominant functional gastrointestinal disorder in the following susceptible groups:

1. Non-functioning small bowel NETs who have never had any treatment
2. Functioning small bowel NET patients on symptom controlling treatment which is not thought to be causing diarrhoea. These patients should be on a stable dose of somatostatin analogues and/or pancreatic enzyme replacement therapy for at least 3 months
3. Small bowel NET patients who are at least 3 months post intestinal surgery/injury /radiotherapy, chemotherapy PRRT, molecular targeted therapy (sunitinib, everolimus) or interferon
4. Pancreatic NET patients who have undergone the whipples operation with small bowel involvement and are at least 3 months post surgery
5. Smaller pancreatic functioning NET patients who have stable disease on somatostatin analogues

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

Patients must NOT have:

1. Diarrhoea directly related to uncontrolled hormone secretion of the tumour
2. Steatorrhoea due to insufficient pancreatic enzyme use (starting dose is 25,000 units lipase per meal, titrated up to 75,000-80,000 units lipase per meal)
3. Bile salt malabsorption
4. Short bowel syndrome
5. Any gastrointestinal disease other than a NET
6. Have constipation as the predominant symptom
7. Bacterial overgrowth in the past 4 weeks
8. Been on antibiotics in the past 4 weeks
9. Been on any lactulose, prebiotic or probiotic in the past 4 weeks
10. Had changes to any IBS medication in the past 4 weeks
11. Have had bowel preparation or investigative procedures in the past 4 weeks
12. Be pregnant or lactating
13. Diabetes, current eating disorders or psychiatric illness
14. A poor level of English skills

### **Date of first enrolment**

28/01/2014

### **Date of final enrolment**

31/12/2016

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

The Royal Free Hospital

London

United Kingdom

NW3 2QG

# Sponsor information

## Organisation

The Royal Free Hospital (UK)

## ROR

<https://ror.org/01ge67z96>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

The Royal Free Hospital (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |

