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

Submission date
23/11/2015

Recruitment status
No longer recruiting

Registration date
11/12/2015

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 stablilty. 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 recieved 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
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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 (sunitunib, 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?
HRA research summary			28/06/2023	No	No