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Novel management of symptoms in patients with irritable bowel syndrome

Submission date
26/11/2019

Recruitment status
No longer recruiting

Registration date
14/07/2020

Overall study status
Completed

Last Edited
24/04/2025

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome (IBS) affects up to 1 in 5 people in Britain. IBS can have a huge impact on a sufferer's daily activities, general wellbeing and overall health. IBS often carries major financial implications because of time lost from work, the cost of attending GP appointments and prescriptions. Sufferers also often report substantial extra ongoing costs for things like over-the-counter medicines, incontinence pads, deodorants, extra lavatory paper and laundry. IBS does not just affect sufferers, their work, family and friendships. Treating IBS costs the NHS much more than £100 million annually.
The National Institute for Health and Care Excellence (NICE) guides how tests and treatments for diseases should be used. For IBS they recommend that the diagnosis can be made if someone has typical symptoms and normal results from four blood tests. More detailed tests used by specialists, NICE says, are not needed. Once IBS is diagnosed, NICE recommends lifestyle and dietary changes and/or medicines although they admit that the evidence that these things help is weak. Indeed, NICE acknowledges that when their recommended treatments are used, at least half of sufferers continue with long term troublesome symptoms. The problem is that "typical IBS symptoms" and four blood tests are an unreliable way to distinguish patients with true IBS from those with other conditions which cause symptoms similar to IBS. Evidence suggests that most people with constant or intermittent diarrhoea diagnosed as IBS, in fact, have a different diagnosis which the NICE recommended tests do not pick up. Examples of very treatable, often missed diagnoses and the number of affected people include:
1. Sensitivity to fat in diet: 1 in 4 patients
2. Abnormal digestion of sugars: 1 in 4
3. Germs living in parts of the bowel where there should be no germs: 1 in 4
4. Microscopic bowel inflammation: 1 in 10
5. Pancreas gland working inadequately: 1 in 20
The aim of this study is to measure the benefit for the patient of care delivered by a GP following NICE recommendations compared to care given by a specially trained nurse.

Who can participate?
Patients who the GP considers are likely to have IBS, have not been previously investigated for this and have intermittent or constant diarrhoea

What does the study involve?
If patients agree to take part in this study, they will be assigned to one of two groups at random. The results from each group will be compared at the end of the trial. Neither the patient, doctor nor nurse can choose to which group any patient are allocated. Half the people taking part in our study will be allocated to care delivered by the GP following NICE recommendations for the treatment of IBS-like symptoms and half by a specially trained nurse who will organise some additional tests. The nurse will arrange a simple series of tests focusing on identifying whether the treatable conditions listed above are present and offering specific treatments based on the test results. The researchers will measure which group improves the most and the cost for the patients and the NHS of this approach. They will follow the patients for a year to see whether any improvement achieved continues long term.

What are the possible benefits and risks of participating?
The main disadvantage for everyone taking part is the extra time required to fill out the questionnaires on two occasions and keep a diary of the cost of having these symptoms and all the attendance for tests and appointments. There will also be extra time required for the tests performed for those who are allocated to the group where care is provided by the nurse. It is not known whether it is better to do these tests, and so they may prove not to be helpful. None of the tests the nurse might arrange are unusual or experimental, however, they are generally not offered to people with IBS. They are all standard tests used frequently in other conditions. There is no risk involved with filling out questionnaires, providing breath samples or stool samples. Minor pain and bruising can occur with blood sampling. The nuclear medicine scan to detect a sensitivity to the amount of fat in the diet is a two-part test. On the first visit to the department participants will be asked to swallow a capsule which contains an artificial bile acid which is linked to a very small amount of radioactivity. The amount of radioactivity is equivalent to about the same amount that people are exposed to in their daily lives over a 1- to 2-month period. After they have swallowed this capsule, participants will be asked to wait for about 3 hours. Then they have a scan using a special camera to measure the tiny amount of radioactivity in their body - this takes about 15 minutes. Afterwards, they will be free to go but will be asked to return after 1 week when the scan will be performed a second time. The difference between the amount of measured radiation between the first and the second scan will show whether they have bile acid malabsorption, a condition which often mimics IBS, and what sort of treatment is likely to help them most of all. The amount of radioactivity in the capsule is so little that participants do not need to avoid any activity or being with people while the test is taking place. However, the test should not be performed on anyone who is or could be pregnant in the next 3 months. Potential risks from the telescope examination (flexible sigmoidoscopy) include heavy bleeding or tearing of the bowel wall. These problems occur in fewer than 1 in 10,000 people, and are detailed in the standard information booklet on flexible sigmoidoscopy which will be provided in advance.

Where is the study run from?
Lincolnshire Community Health Services Trust (UK)

When is the study starting and how long is it expected to run for?
May 2020 to October 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Team.research@nhs.net

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-003531-24

Integrated Research Application System (IRAS)
276667

Central Portfolio Management System (CPMS)
44804

Study information

Scientific Title
Organic disease masquerading as irritable bowel syndrome: a randomized controlled trial in primary care: the Lincolnshire POACHER study (Promoting Optimal Assessment to Change Health and Engineer an Economic Revolution)

Acronym
POACHER

Study objectives
The majority of patients with irritable bowel syndrome (IBS)-like symptoms characterised by diarrhoea, have missed organic pathology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2020, West of Scotland Ethics Committee 4 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), REC ref: 20/WS/0029

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
Randomisation will be performed independently by the Hull Health Trials Unit:
Arm 1: Controls: standard GP treatment following NICE guidance for the treatment of IBS-like symptoms.
Arm 2: Intervention arm: experimental investigations and treatments, nurse-led treatment following checklists and arranging additional investigations.

The patients will be followed for 1 year following randomisation.

Treatment will be given as necessary in both arms. The primary endpoint will be improvement in symptoms at 1 year.

Intervention Type
Mixed

Primary outcome(s)
IBS symptoms measured using the IBSSSS questionnaire at 1 year

Key secondary outcome(s))
1. Economic evaluation of healthcare and patient costs at 1 year:
1.1. NHS costs calculated from electronic patient records for the year that the patient is included in the study
1.2. Patient costs related to their IBS-like issues calculated with a monthly economic evaluation filled in by the patient for the year they are in the study
1.3. QALYs assessed using EQ5DL at 1 year
2. Quality of life measured using Modified GSRS, IBSSSS, SF12, EQ5D3l at 1 year
3. Time to symptom improvement measured using patient records at 1 year
4. Conditions diagnosed measured using patient records at any time from randomisation to end of 1-year follow-up

Completion date
31/10/2023

Eligibility

Key inclusion criteria
Patients presenting to the GP with IBS-like symptoms characterised by intermittent or constant loose stool

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unexplained weight loss, rectal bleeding, fever, anaemia, palpable mass or sudden unexplained onset of symptoms
2. Previous referral for chronic GI symptoms to a gastroenterologist or GI surgeon
3. Previous cholecystectomy
4. Previous gastrointestinal surgery of any type except appendicectomy, abdominal wall or femoral hernia repair or diagnostic laparoscopy without surgical intervention
5. Past history of inflammatory bowel disease, coeliac disease, chronic liver or pancreatic disease
6. Past history of cancer (except basal cell carcinoma)
7. Consultation with any health professional in the last 5 years for abnormal GI symptoms
8. Previous investigations in secondary care for IBS-like symptoms

Date of first enrolment
01/09/2020

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lincolnshire Community Health Services NHS Trust
Beech House
Witham Park
Waterside

Lincoln
United Kingdom
LN5 7JH

Sponsor information

Organisation
Lincolnshire Community Health Services NHS Trust

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No

Participant information sheet	version V2	10/03/2020	14/07/2020	No	Yes
Participant information sheet	version 4	01/09/2020	14/05/2021	No	Yes
Protocol file	version V1	21/01/2020	14/07/2020	No	No
Protocol file	version 2.3	09/03/2021	14/05/2021	No	No
Protocol file	version 2.6	21/03/2023	23/01/2024	No	No