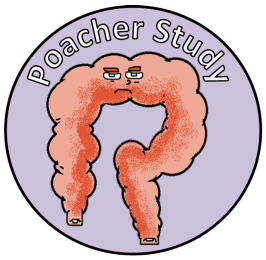

NHS
Lincolnshire Community Health Services
NHS Trust

Patient Information Sheet for the Lincolnshire Poacher Trial

Introduction

We would like to invite you to take part in our research study. Before you make a decision we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Ask us if there is anything, which is unclear to you, or if you would like more information. Do take time to read this sheet, think about the study and discuss the study with family or friends so you can decide whether or not you wish to take part. Thank you for taking the time to read this.

Why have I been invited to take part?

You have been invited to take part in this study because your symptoms are thought by your GP to be due to a condition called "irritable bowel syndrome" which is often called "IBS". This is a common condition, which may affect as many as 1 in 5 people in the UK.

When diseases are common, the Department of Health asks the National Institute for Health and Care Excellence also known as "NICE" to make recommendations as to the best way of looking after people who have that disease. For people coming to their GP with symptoms of IBS, NICE recommends that the diagnosis can be made if someone has typical symptoms and abnormal results from four blood tests.

This study aims to show whether additional tests and treatments might help people with IBS more than the current approach does.

What is the purpose of the study?

We are carrying out this scientific study in 134 patients recruited from GP surgeries across Lincolnshire. We are looking for people who have diarrhoea or loose bowel movements at least sometimes as well as other symptoms which their GP feels makes the diagnosis of IBS likely. You have been offered this study because you have these types of symptoms.

Do I have to take part?

No, it is up to you whether or not you decide to join this study. We will describe the study and go through this information sheet with you. If you agree to take part we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. If you decide to take part, or not to take part, your usual treatment will not be affected in any way.

What will happen to me if I take part?

After signing the consent form confirming you understand what this study involves and that you agree to take part in this study, you 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 you, your doctor nor your nurse can choose to which group you are allocated. The group to which you are allocated is chosen by a computer. This helps avoid any bias that anyone may have about which group is best. This type of research study is called a randomised, controlled trial.

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. This study will compare what happens to patients who are looked after by the GP compared to those looked after by the nurse.

During our study, we will measure your symptoms, and the cost for you and the NHS of both approaches. We will follow you up for one year, to see whether any improvements achieved continue long term.

All people taking part in the study will be asked to complete several questionnaires at the start of the study (this will take about 20 minutes) and one year later, which will measure how they feel and what has happened to their symptoms. We also request that all people taking part complete a diary once a month to record any extra costs they have had to pay because of their symptoms.

All participants in the trial will be asked to have some blood tests. If you are allocated to the group looked after by the GP, as long as these blood tests are normal, the GP will suggest that you try some treatment. This may include suggestions how you could change your diet or the GP might recommend you should try one or more of a range of medications which NICE suggest may help your symptoms and are the standard treatments used to help people with IBS-like symptoms.

If you are allocated to the group cared for by the nurse, as long as these blood tests are normal, you will be seen in your GP's surgery and at that stage will be asked to complete additional questionnaires about what you eat and drink. You will also be asked to provide a stool sample which will be tested for a number of different possible conditions. You will have a breathing test arranged to see if you might have germs living in parts of the bowel where there should be no germs.

If these tests do not show a cause for their symptoms, then you will have a scan arranged to see if you are sensitive to fat in your diet. If that is normal, you will have one further breath test to see if you are sensitive to specific sugars in your diet. If all these tests are normal, then a telescope test through the mouth to examine the upper gut and a second limited telescope to examine the lining of the lower bowel will be arranged. If that is normal, the nurse will recommend trying a special diet which you will be taught and helped to follow. Please be aware that these further tests will be arranged subject to Coronavirus/Service resumption.

If any test is abnormal, the nurse will offer you specific treatments based on the test results. No further tests will be arranged unless the treatment suggested has not worked. Treatments may involve lifestyle advice and/or dietary changes and/or medications.

At the end of the study a selection of people treated by both the GP and the nurse will be invited to an interview (this may be face to face, over the phone or over the internet) to see how they feel about the treatment they received. This interview is likely to take 30-60 minutes.

If any test, at any stage, is abnormal, participants looked after by the nurse will be treated for that abnormality before deciding if they should receive any further tests. If that treatment makes their abnormal symptoms go away they will not receive any further tests.

What are the disadvantages and possible risks of taking part?

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 arm of the trial where care is provided by the nurse. We don't know 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 your diet is a two part test. On the first visit to the department you 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 we are all exposed to in our daily lives over a one to two month period. After you have swallowed this capsule, you will be asked to wait for about three hours. Then, you have a scan using a special camera to measure the tiny amount of radioactivity in your body - this takes about 15 minutes. Afterwards, you will be free to go, but will be asked to return after one 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 tell us accurately whether you have bile acid malabsorption, a condition which often mimics IBS, and what sort of treatment is likely to help you most of all. The amount of radioactivity in the capsule is so little that you 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 (gastroscopy and flexible sigmoidoscopy) include heavy bleeding or tearing of the stomach or 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.

What are the possible benefits of taking part?
There may be no direct benefit to you from taking part in this study, but the results may benefit other people in the future. If you are allocated to the study group cared for by the nurse, and if you have a test which diagnoses a condition which the GP could not diagnose following the recommendations of NICE, then you may receive effective treatment a lot sooner.

What happens when the research study stops?
Your normal care will continue in the usual way and any treatments prescribed by the nurse which you find helpful will be prescribed by your GP, if you need them long term.

When this study finishes, all participants will be offered a summary of the study findings. If the trial identifies that some tests are particularly helpful, the participating GPs will be able to refer those people with continuing symptoms to have those tests if they have not had them. If the trial shows that people allocated to the nurse group have a better outcome, the local Clinical Commissioning Group, the body that funds local health care have guaranteed that this approach will be developed as the standard approach across all GP surgeries in Lincolnshire.

Will my taking part in the study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential and held securely and only members of the research team will have access to your information. However, your GP will be informed about your participation in the study and will be told about your test results and any treatments you need either in the short or the long term.

Your data from this study will be kept in such a way so that you cannot be identified. The data will be stored securely according to the regulations of Lincolnshire Community Health Services NHS Trust and the General Data Protection Act 2018 (GDPR). Paper records stored in secure and locked offices, and electronically on a secure web-based database managed by the Hull Health Trials Unit.

How will your personal data be used in this study?
Your GP will tell you about this study and if you are interested will pass on your contact details to the research team who work for the Lincolnshire Community Health Services NHS Trust.

If you agree to take part, a copy of your consent form with your name on it will be sent via the secure web based database to the Hull Health Trials Unit who will look after all data collected for this study. Only designated research team members will see the consent form.

Your rights to access or change the information you provide are limited. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The research team will use your name and contact details to contact you initially about the research study. You will be assigned an unique participant identification number when you are enrolled into the study and all data collected from you over the course of the study will be stored under this number. Only your local research/medical team will know to whom a unique study number has been allocated.

Members of the research team at Lincolnshire Community Health Services NHS Trust and authorised people from regulatory organisations may look at your medical and research records to obtain further details of your tests and treatments and to check the accuracy of the research study data.

What will happen to the information from the study?

Any identifiable information collected about you will be kept confidential and secure, disclosed only with your permission, or except as required by law. Lincolnshire Community Health Services NHS Trust will keep identifiable information about you for a maximum of 12 months after the study has finished and results published.

The people who analyse any information resulting from the study will not be able to identify you and will not be able to find out your name or contact details. Your name will not appear on any materials produced from this study and it will not be possible to identify you from any publications which result from this study.

The results will be published in scientific journals and publicised so that people everywhere can benefit from hearing the results of this study. Data from this study may be shared with other researchers who are doing research approved by an ethics committee but if the data are shared, it will not be possible to identify you from that data.

All anonymised research data will be kept securely for a minimum of 10 years after completion of the research.

Where is your data stored?

Your personal data will be processed and stored by authorised staff and study researchers the Hull Health Trials Unit using REDCap Cloud and BOX.com. Further information about how we use your information and how it is stored can be obtained by contacting Professor Andreyev who is organising this study or the research nurses who are running the trial.

Who is organising and funding the research?

This trial has been developed by a group of doctors, nurses and patients based at Lincoln County Hospital, with input from local GPs, researchers at Lincoln University, and Anglia Ruskin University and Hull Health Trials Unit at the University of Hull. This research study is run and sponsored by the Lincolnshire Community Healthcare Services NHS Trust. The funding to pay for this trial was won after a competitive bid to the Research for Patient Benefit funding stream of the National Institute for Health Research, UK.

What if something goes wrong?

In the unlikely event you are harmed during the research and this is due to someone's negligence, you may have grounds for legal action for compensation against Lincolnshire

Community Healthcare Services NHS Trust but you may have to pay the legal cost. The normal NHS complaints procedure will still be available to you and as a first step you may wish to contact the Patient Advice and Liaison Service, Lincolnshire Community Health Services NHS Trust, Beech House, Witham Park, Waterside South Lincoln LN5 7JH Telephone: 0300 123 9553 email: LHNT.LincsPALS@nhs.net

Who has reviewed the study?

This study has been reviewed and approved by independent reviewers at the National Institute for Health Research, the Lincolnshire Community Healthcare Services NHS Trust and an approved ethics committee.

Further Information

If you volunteer to take part in this study, we are unable to refund you for any expenses incurred for taking part. Before you make a decision about your participation in this study, remember that you can ask us any questions. Allow yourself as much time as you need to think through your decision. If you then decide that you still wish to take part, you will be asked to confirm in writing that you have read and understand this patient information and that all of your questions have been answered completely and that you wish to continue in the study.

If you would like further information about the study, or have any concerns during the study, please contact the research nurses running this study. Their phone number is 01522 308808. Alternatively, you can contact Professor Jervoise Andreyev Tel: 01522 707473 who is the chief investigator running this study. The study team will be happy to discuss any aspect of this study with you.