Colonoscopy Research Project: Participant Information Sheet

Chief investigator – Professor Colin Rees

Dear Patient,

We would like to invite you to take part in a research study, the COLO-DETECT Study. Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you. It will not involve any financial cost to you. Please take some time to read the following information carefully. You are welcome to talk with others such as family, friends, or your own GP about the study if you wish. Your participation in the study is entirely voluntary and you can change your mind at any time. Your decision to participate or not will not influence your current or future care in any way.

This sheet will explain what the purpose of the study is, give more detailed information about the way the study will be conducted, and describe what will happen to you if you choose to participate.

Please ask us if there is anything that is not clear or if you would like more information (contact details for the research team are at the end of this information sheet).

Thank you for taking the time to read this information sheet.

What is the background to this study?

In the UK, around 1 in 15 men and 1 in 18 women will develop bowel cancer in their lifetime. Most bowel cancers develop from a type of polyp – called an adenoma – that becomes cancerous. It is important to find as many polyps as possible to decide whether they need to be removed, as this may prevent a polyp becoming cancerous in the future. The best tool that doctors use to find and remove polyps is colonoscopy (large bowel camera test), but it is not perfect and there is an ongoing search to make it better.

The GI Genius™ is a type of artificial intelligence device which is designed to help the person performing the camera test to find more polyps. The GI Genius™ is a box that is connected to the normal colonoscopy equipment, which analyses the images from the camera in real time. It highlights any areas it thinks may contain a polyp within a green box which appears on the screen that the person performing the camera test can see. These areas can then be inspected more closely to determine if a polyp is present and whether it should be removed.

What is the purpose of this study?

The purpose of this study is to find out if using the GI Genius™ will help colonoscopists to find polyps, and find more of them, than they find when they don't use GI Genius™. We know that finding pre-cancerous polyps and removing them reduces the risk of bowel cancer. Therefore, if the GI Genius™ helps colonoscopists to find and remove more polyps, the risk of bowel cancer in their patients should be reduced. There will therefore be two groups of patients in this study: those who have a colonoscopy with GI Genius™, and those who have a colonoscopy without it (i.e., a standard colonoscopy). People who decide to participate will be randomly allocated to one of the two groups and it is not possible to decide which group a participant will be in before they decide to take part.

The study will also assess if colonoscopies performed using the GI Genius™ take longer when compared to procedures performed without the GI Genius™.

Why have I been invited?

You have been invited because you have been referred for a colonoscopy, usually this will be because of bowel symptoms, for surveillance (checking for new or further problems) after a previous colonoscopy, or as part of the national Bowel Cancer Screening Programme.

Am I the only person involved in this study?

This study is aiming to recruit just over 2000 patients who have been referred for a colonoscopy as part of their usual care, from the 9 hospital Trusts that are taking part.

Do I have to participate?

No. The decision to take part is completely up to you. If you do decide to take part, you will be asked to sign a consent form to confirm this. Even after this you are free to change your mind at any time and this will not affect your current or future care in any way.

What are the possible benefits of taking part?

If you are allocated to the GI Genius™ group, the colonoscopist performing your procedure may be able to find more polyps as a result of you being in the study. If this is the case, and they are pre-cancerous (adenomas), then removing them may reduce your risk of developing bowel cancer in the future.

What are the possible negative effects of taking part?

It is possible that your colonoscopy may take slightly longer due to more polyps being found, inspected, and possibly removed, however these polyps were there anyway, all we have done is identified them. Each polyp removal carries a small risk of complications (bleeding and perforation), so if more polyp removals are required, the overall risk of complications during the procedure will be slightly higher.

If I decide to take part, how do I tell you, and what will I have to do?

You should have received this leaflet after you were referred for a colonoscopy. At some point in the week prior to the date of your colonoscopy one of our research team will give you a telephone call to ask if you are interested in participating. If you are not, please simply tell the research nurse this (it will be one of the first things they ask you) and we will end the telephone call and will not contact you about the study again.

If you decide ***not*** to take part, you have to do nothing else, and your colonoscopy will be performed entirely as normal for the hospital where you are having your procedure, and your care will not be affected in any way.

If you ***do*** decide to take part, you will be asked a few simple questions to confirm that there are not any reasons why you should not participate, including:

- Whether or not you are pregnant
- The reason for your colonoscopy
- Your medical history
- Your current medication

If there are no reasons why you should not participate, you will then be asked for your verbal agreement to participate.

On the day of your colonoscopy, one of the research team will meet you in the hospital just before your procedure to check whether you have any more questions and – if you would still like to participate – ask you to sign a consent form to confirm that you have understood the information regarding the study and that you agree to participate. This form is separate to the consent form for the colonoscopy itself, which will be discussed with you by the team performing the colonoscopy. The research team member will also ask you to complete a very short (<1 minute) questionnaire indicating your perceptions of your health-related quality of life. You will also be given one of these to complete on the day after your colonoscopy to see if there is any change.

We will then use a computer programme to randomly tell us whether GI Genius™ will be used in your colonoscopy or not. If you are assigned to the GI Genius™ group, your colonoscopy will be as normal for the hospital where you are having your procedure, except that for all or part of the procedure you will be able to see some green markers in the corners of the screen and a green box may occasionally appear on the screen. If you are assigned to the non-GI Genius™ group your colonoscopy will be as normal for the hospital where you

are having your procedure. For all participants, the nursing team will record some of the details of your colonoscopy during the procedure, including:

- How long it took to reach the furthest point of your large bowel
- How long it took to take the colonoscope out
- Details of any problems during the test

We will assess your comfort during the test, based on the perceptions of the colonoscopist (person performing the camera test) and the nurses caring for you. Once your colonoscopy is finished, the procedures for observing you for a period to make sure you remain well and discharging you from the hospital will be the same as they normally would.

We will invite you to complete 2 questionnaires that allow you to tell us about your experience of colonoscopy and your health-related quality of life in more detail. The health-related quality of life questionnaire is a repeat of the one you will be asked to complete just before your colonoscopy. These will be given to you to complete the next day and post back to the study team at South Tyneside District Hospital (in a prepaid envelope).

We will ask if we have your permission to follow up what happens to you over a long period of time (up to 5 years), by accessing certain parts of your medical notes and health related records relevant to the study, but we will not need to contact you directly to do this.

- Examples of information sought may include attendances at hospital, whether you were diagnosed with any significant illnesses, or other health outcomes. The research organisation may access details and information from health records from national organisations such as NHS digital, cancer registries and admissions, hospital attendance data, GP records or similar records to look at your health status. Data may also be linked with other appropriate research databases where necessary (such as the CORECT-R study – a national project by Edinburgh University to quantify the characteristics of, and any variation in, colorectal cancer and its management). Limited information such as your date of birth or NHS number, that identifies you, may be sent to these national organisations to allow the information to be linked together. Only relevant information or parts of your medical records will be accessed or linked. This will occur periodically and remotely and will not involve any effort on your part. Any researcher who may be accessing your health records will do so in confidence with your consent from this study and will observe best ethical and legal practice.

Follow up

Any follow up appointment you have as part of your routine care will not be affected by taking part in the study. Results from your colonoscopy will be reviewed by the doctor/team that organised your colonoscopy.

After 14 days a member of the local research team may contact you via telephone to find out if you have remained well since the colonoscopy. We will also review your medical notes to gather any further information we need. If you required any hospital attention after your colonoscopy but attended a different hospital to where you had your colonoscopy, we may contact your GP or the hospital where you were admitted, to obtain information regarding that hospital visit. This is to make sure we do not miss out any problems that you might have experienced because of your colonoscopy. If your questionnaires have not been received through the post by this time the research team will also ask whether you have completed them, and/or whether you need additional copies which would then be sent to you.

The local research team may send you one further reminder to return the questionnaires 2 weeks after this, where the questionnaires have not been received. If you receive a reminder after you have posted your questionnaires to us, please accept our apologies, and ignore the letter.

What will happen with my information and will it be kept confidential?

South Tyneside and Sunderland NHS Foundation Trust is the sponsor for this study and is based in the United Kingdom. We will be using information from you and your medical records to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Any person that handles your data will be accountable against NHS and common law confidentiality principles and standards, as well as the 2018 Data Protection Act and UK GDPR regulations.

[NHS site] will collect information from you and your medical records for this research study in accordance with our instructions. [NHS site] will keep your name, hospital number, date of birth and contact details confidential. [NHS site] will use this information as needed, to contact you about research, and make sure the relevant information about the study is recorded for your care, and to oversee the quality of the study. [NHS site] will create a unique code assigned to you for this study. Data collected as part of this study will be anonymised, and stored on a secure database, which is created and maintained by North Wales Organisation for Randomised Trials in Health Clinical Trials Unit (NWORTH CTU); they will also be responsible for analysing the data once enough participants have had a colonoscopy. NWORTH CTU will only receive information with your unique study code without any identifying information (such as name, hospital number, date of birth). If we share the data with other researchers working on this study, it will contain only your unique code with no identifiable information.

Certain individuals from South Tyneside and Sunderland NHS Foundation Trust, Newcastle University, and regulatory organisations may look at relevant sections of your medical and research records to check the accuracy of the research study. Additionally, to enable us to follow up your health records over time, limited information such as your NHS number or date of birth will need to be shared with the research organisation to allow data linkage.

[NHS site] will keep identifiable information about you from this study for 15 years, before ensuring it is securely destroyed, according to rules relating to the storage of research data. Any information transferred away from the study site to any of the organisations identified above, for the purposes already described (except that limited information which helps us the research team to follow up relevant sections of your health records over time), will be anonymised and will also be kept for 15 years before being securely destroyed. You have the right to opt out of having your data linked to other healthcare databases; you will be asked to indicate your preference regarding this in point 9 of the consent form.

Your rights to access, change, or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep and may use the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

Please note under the Data Protection Act 2018, you have the right to erasure (also known as the 'right to be forgotten'). Should you wish for us to erase the data we hold about you in relation to this study, you can contact us by telephone or in writing using the details at the end of this information sheet, and we will respond to your request as required by law. There are some exceptions to this; for example, we cannot erase

the data specifically relating to your clinical care or that is essential for ensuring your safety, but we can erase data from the research database. We will detail and explain any exceptions in our response to your request for erasure.

You can find out more about how we use your information at -

www.hra.nhs.uk/information-about-patients/

https://www.stsft.nhs.uk/research-and-innovation/research

https://www.stsft.nhs.uk/patients-and-visitors/caring-our-patients/how-we-use-your-information

Email [add local Data Protection Officer email]

Will anyone else be told about my participation in this study?

We will inform your GP about your participation in the study. Please feel free to discuss your participation in the study with friends or your family if you choose to do so.

Can I withdraw from the study at any time?

Yes. You are free to decline to join the study, or, if you agree to participate, you may withdraw at any time during the study. This will not affect your care in any way. If you choose to withdraw from this study any data collected about you as part of the study up until that point, will be kept and used in the same way as described in the 'What will happen with my information and will it be kept confidential?' section above.

What if something goes wrong?

We do not believe that there are any risks of harm due to participation (or not) in this study. If you wish to complain or have any concerns regarding any aspect of the way you have been treated during this study, then the normal NHS complaints procedure is available. The NHS indemnity scheme is in place in case you suffer any harm or injury because of negligence.

Information concerning your rights as a patient, research-related questions, or research-related injury can be found via the Patient Advice / Information and Liaison Service (PALS / PILS) at the hospital where you had your colonoscopy. Their contact details are: [input local NHS site address/contact details].

What will happen to the results of the research study?

The results of the study will be published in one or more papers in medical journals for the information and education of healthcare professionals. No individual patients will be identifiable from any published report.

Who is organising and funding the research?

The study is organised by Professor Colin Rees, a Professor at Newcastle University and Consultant Gastroenterologist at South Tyneside District Hospital, South Shields, part of South Tyneside and Sunderland NHS Foundation Trust (who are acting as the study Sponsors). Professor Rees has led many large endoscopy trials and is a National Institute of Health Research Senior Investigator.

The study is being funded by Medtronic Ltd. who manufacture GI Genius™. Medtronic do not have any control over the design or conduct of this study.

Who has reviewed the research?

The research protocol has been approved, in advance of the study commencing, by the NHS Research Ethics Committee (REC), the National Bowel Cancer Screening Programme (BCSP) Research Committee, and the Research and Development (R&D) committee of each participating hospital. The trial has also been registered on two international databases of clinical trials, which supports accountability (ClinicalTrials.gov and ISRCTN).

What if I have any further questions?

If you have any further questions or you would like to take part in this study please contact the doctor who is responsible for conducting the trial (Principal Investigator), or the research team, at the Hospital where you are having your colonoscopy:

Principal Investigator: [input local NHS site PI]

Research Team: [input local NHS site Research Team]

[input local NHS site address/contact details]

Thank you for taking the time to read this information sheet.