

PATIENT INFORMATION SHEET

Study title

NICE FIT: NICE guidelines and Faecal Immunochemical Test

Invitation and brief summary

You have been sent this information and kit because we are inviting you to help us research a new test that can rule out bowel cancer. Inviting you does not mean that you have bowel cancer.

What's involved?

At present, there is no easy test to screen for bowel cancer. Patients are referred for a colonoscopy when they have symptoms that might indicate they have bowel cancer. But only 4 patients out of 100 will have a diagnosis of bowel cancer. So a lot of patients are having a colonoscopy where the results will be negative. We do that to try not to miss any "low risk" patients that may have bowel cancer. A new test called FIT (faecal immunohistochemistry test) has shown that it is very accurate at ruling out bowel cancer when it is negative. Other studies have shown it is more accurate than another stool sample test called the faecal occult blood test (FOBT) that has been used for bowel screening.

We want to see whether patients referred for a colonoscopy could instead have a FIT. This requires sampling stool, which may not be pleasant, but carries none of the risks of a colonoscopy. We can then compare the results of the FIT test to the results of your colonoscopy. If it is accurate, in the future a stool test alone would be needed to rule out bowel cancer, and not a colonoscopy and potentially you could be one of those patients. To see if FIT is accurate in our population, we need to test 5,500 patients in West London.

What would taking part involve?

If you agree to take part in this study, a member of our study team will be contacting you to go through the instructions of the kit. This will be your opportunity to ask any questions and sign the consent form. Before your scheduled colonoscopy, you will be asked to take bowel prep to clean the bowel. Few days before you start taking your bowel prep for your colonoscopy, we would like you to sample your stool using the special stool kit. This should not be done more than 2 days before your colonoscopy. Please follow the illustrated instruction leaflet in the bag with the kit. Once collected, please store in a cool dry place until it is posted to the lab for analysis, using the supplied self-addressed prepaid envelope

What are the possible benefits of taking part?

This research will not affect your test results, any subsequent treatment, and has no direct benefits to you on this occasion. You will already be receiving the gold standard investigation which is a colonoscopy.

However, this research could benefit you or people with similar symptoms in the future. A negative result from a stool sample could rule out bowel cancer in some patients, and prevent them from needing a colonoscopy.

This will also save the NHS time and money from not having to carry out unnecessary colonoscopies.

What are the possible disadvantages and risks of taking part?

There are no risks to taking a stool sample, although it may be considered unpleasant!

Further supporting information

Why are we asking you to give us a stool sample?

We are asking you to give us a stool sample so that we can compare the results of the test with the results from your colonoscopy.

What do I do if I have further questions?

Please contact the investigator Nigel D'Souza on his e-mail or phone number below.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any point and this will not affect your treatment.

How will my information be kept confidential?

All of your personal details will be kept confidential. Your samples will be analysed at the Bowel Cancer Screening Hub in Guilford and will only be identified by a unique number. The samples will be destroyed once the research is conducted. Your clinical information is stored in a secured database and coded in such a way as to make it impossible for you to be identified personally.

The samples that you provide will be used for research purposes only. It is highly unlikely therefore that your sample will have commercial value in the future.

What if I want to withdraw from the study?

You may withdraw at any point. We would still use your anonymous data in the study, unless you ask for it not to be used.

What will happen to the results of this study?

The results will be published and spread within the NHS. A summary leaflet will be available once the study is completed. You can also e-mail the investigator Nigel D'Souza for a copy of this.

Who is organising and funding this study?

The study is organised by the department of Colorectal Surgery at Croydon University Hospital and RM Partners Cancer Vanguard. Alpha labs will provide the FIT analyser and training . They will also provide the raw materials and patient instruction leaflets. NHS England are funding this study through RM Partners.

What will happen to the samples I give?

Once your sample has been processed, it will be destroyed.

Further information and contact details

Mr Nigel D'Souza

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