



The North West London Hospitals
NHS Trust



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Patient Information sheet

Virtual colonoscopy compared with barium enema for diagnosis of bowel disease

We are inviting you to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We want to compare the effectiveness and convenience to you of two procedures that are used to diagnose bowel disease. The method that we have been using up to now at St Marks Hospital is called a barium enema. Barium enema involves filling the bowel with barium liquid and then gas, and then taking x-rays of it in order to see any abnormalities. Recently, a new type of x-ray CT scan called 'virtual colonoscopy' has been developed that is as good at diagnosing disease and may be more convenient for the patient. A few NHS hospitals are already offering virtual colonoscopy to patients instead of barium enema. The NHS has sponsored this research project in order to find out if this test should replace barium enema. The research is being carried out in 15 NHS hospitals and will involve 2,000 patients who will be allocated randomly to receive either the barium enema or the virtual colonoscopy. This way we will be able to find out which works best both for doctors and patients.

Why have I been chosen to take part in the study?

You have been chosen because your doctor has referred you for a bowel examination to find out the reason for your symptoms.

Do I have to take part?

No. It is up to you to decide whether or not to take part in this research. If you decide not to, you will get the barium enema. If you do decide to take part then there will be a random decision to give you either the barium enema or the virtual colonoscopy. We recommend that you keep this information sheet. You can withdraw at any time, or decide not to take part, which will not affect the usual standard of care you receive.

What will happen to me if I take part?

One third of our patients will be given the virtual colonoscopy and two-thirds will have the barium enema, **which is the same test you would have if you did not take part in this research. You will therefore have a one in three chance of having a virtual colonoscopy.** The test you will be offered will be decided by a computer, like in a lottery – **you cannot decide what test you will have.**

Both tests involve taking laxative medicines the day before in order to clear the bowel out. Both tests are performed with you lying down and both involve an injection to relax your bowel.

- For barium enema a doctor or nurse radiographer places a tube just inside your back passage and introduces some barium liquid and then carbon dioxide to inflate the bowel. You will turn into several different positions while x-rays of the bowel are taken. The whole examination takes about 20 to 30 minutes. You will then be free to go.
- During virtual colonoscopy a smaller tube is placed just inside your back passage and, as with barium enema, some carbon dioxide is introduced through this in order to inflate the bowel. One difference for you is that no liquid is used. Two x-ray CT scans are then taken, one with you lying on your

tummy and one with you lying on your back. Each CT scan takes about 20 seconds and you will be asked to hold your breath during this. The whole examination takes about 20 minutes. You will then be free to go.

Whichever test you have, you will need to come back for your out-patient appointment with your doctor to get the results. Whichever test you have, the results

will be handled by your doctor exactly as normal and will also be transferred to a research office at St. Mark's Hospital in London. At various stages up to **three months** after, we will ask your opinion of the test that you received. We will ask you to fill in some short questionnaires that we will send to you along with a stamped-addressed envelope for return.

What are the side effects of taking part?

Neither procedure has any common serious side-effects.

What are the possible disadvantages and risks?

Both the barium enema and virtual colonoscopy use x-rays but both are well within official safe limits for medical procedures. However, the dose of radiation for virtual colonoscopy is slightly higher than that for the barium enema. **The virtual colonoscopy also looks at organs outside the bowel. This has possible advantages (e.g. disease elsewhere may be detected earlier) and disadvantages (e.g. you may need further tests if the virtual colonoscopy shows something elsewhere that you doctor thinks is important).**

What are the benefits?

Both tests are well-established and you will get the best possible care whichever test you have.

What if new information becomes available?

If the virtual colonoscopy test comes out as being better for diagnosis, or more convenient for patients, then we will be able to switch to this test for future investigations.

What if something goes wrong?

If taking part in this research project harms you then usual NHS compensation arrangements apply. If you are harmed due to someone's negligence then you may have grounds for legal action. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, then we would like to hear from you and would ask you to contact us directly. Also, the normal National Health Service (NHS) complaints mechanisms are available to you.

Will my taking part in this study be kept confidential?

All information about you collected during the course of the research will be kept strictly confidential and available only to your hospital doctor and the study researchers. **During the trial period, your contact details and the results for your investigations will be held on a secure database at St Marks Hospital, a National hospital for Colorectal Diseases.** Any information about you that leaves your hospital will comply with the Data Protection Act and only authorised study researchers will have access to this information. Your GP will be notified of your participation in the trial.

What will happen to the results of the research study?

The results following completion of the study will be published in medical journals. Further information can be obtained from Professor Steve Halligan, St Marks Intestinal Imaging Centre. You will not be identified from the publication. The results of this research will be used by the NHS to decide whether to use the virtual colonoscopy test instead of barium enema.

Who is organising the research?

This research is being organised by Professor Steve Halligan, a consultant radiologist at St Mark's Hospital, London, in association with other doctors across the United Kingdom, including many working at Cancer Research UK. The research is happening at 15 hospitals.

The study has been reviewed by the NHS Central Office for Research Ethics Committees (COREC) and the NHS Health Technology Assessment (HTA) Programme is funding this research. The doctors and nurses are not being specially paid to do this research.

If you have further questions or require further information please contact Reshma Kanani (Trial Coordinator), on 020 8235 4253.

Thank you for reading this and taking part if you agree.



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Virtual colonoscopy compared with conventional colonoscopy for diagnosis of bowel disease

We are inviting you to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We want to compare the effectiveness and convenience to you of two procedures that are used to diagnose bowel disease. The method that we have been using up to now at St Marks Hospital is called colonoscopy. Colonoscopy involves inserting a tube into the bowel so that the doctor can see inside in order to see any abnormalities. Recently, a new type of x-ray CT scan called 'virtual colonoscopy' has been developed that is as good at diagnosing disease and may be more convenient for the patient. A few NHS hospitals are already offering virtual colonoscopy to patients instead of conventional colonoscopy. The NHS has sponsored this research project in order to find out if this test should replace conventional colonoscopy. The research is being carried out in 15 NHS hospitals and will involve 2,000 patients who will be allocated randomly to receive either conventional colonoscopy or the virtual colonoscopy. This way we will be able to find out which works best both for doctors and patients.

Why have I been chosen to take part in the study?

You have been chosen because your doctor has referred you for a bowel examination to find out the reason for your symptoms.

Do I have to take part?

No. It is up to you to decide whether or not to take part in this research. If you decide not to, you will get conventional colonoscopy. If you do decide to take part then there will be a random decision to give you either conventional colonoscopy or the virtual colonoscopy. We recommend that you keep this information sheet. You can withdraw at any time, or decide not to take part, which will not affect the usual standard of care you receive.

What will happen to me if I take part?

One third of our patients will be given the virtual colonoscopy and two-thirds will have the conventional colonoscopy, which is the same test you would have if you did not take part in this research. You will therefore have a one in three chance of having a virtual colonoscopy. The test you will be offered will be decided by a computer, like in a lottery – you cannot decide what test you will have.

Both tests involve taking laxative medicines the day before in order to clear the bowel out. Both tests are performed with you lying down and both involve an injection to relax your bowel.

- For conventional colonoscopy a doctor places the colonoscope tube inside your back passage and looks around while moving it along the bowel. You may be given a sedative injection to make you a little drowsy. The whole examination usually takes about 20 minutes but can take longer. If you have been given a sedative you will need to wait for this to wear off before you can go. This usually takes about an hour.
- During virtual colonoscopy a smaller tube is placed just inside your back passage. Some carbon dioxide is introduced through this in order to inflate the bowel. One difference for you is that no sedative is given. Two x-ray CT scans are then taken, one with you lying on your tummy and one with you

lying on your back. Each CT scan takes about 20 seconds and you will be asked to hold your breath during this. The whole examination takes about 20 minutes. You will then be free to go.

Whichever test you have, you will need to come back for your out-patient appointment with your doctor to get the results. Whichever test you have, the results will be handled by your doctor exactly as normal and will also be transferred to a research office at St. Mark's Hospital in London. At various stages up to **three months** after, we will ask your opinion of the test that you received. We will ask you to fill in some short questionnaires that we will send to you along with a stamped-addressed envelope for return.

What are the side effects of taking part?

Neither procedure has any common serious side-effects. However, very rarely, patients having conventional colonoscopy may become over-drowsy with the sedative. Even more rarely, the bowel can be torn by the colonoscope tube. This is very uncommon.

What are the possible disadvantages and risks?

The virtual colonoscopy use x-rays but is well within official safe limits for medical procedures. The virtual colonoscopy also looks at organs outside the bowel. This has possible advantages (e.g. disease elsewhere may be detected earlier) and disadvantages (e.g. you may need further tests if the virtual colonoscopy shows something elsewhere that you doctor thinks is important).

What are the benefits?

Both tests are well-established and you will get the best possible care whichever test you have.

What if new information becomes available?

If the virtual colonoscopy test comes out as being better for diagnosis, or more convenient for patients, then we will be able to switch to this test for future investigations.

What if something goes wrong?

If taking part in this research project harms you then usual NHS compensation arrangements apply. If you are harmed due to someone's negligence then you may have grounds for legal action. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, then we would

like to hear from you and would ask you to contact us directly. Also, the normal National Health Service (NHS) complaints mechanisms are available to you.

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