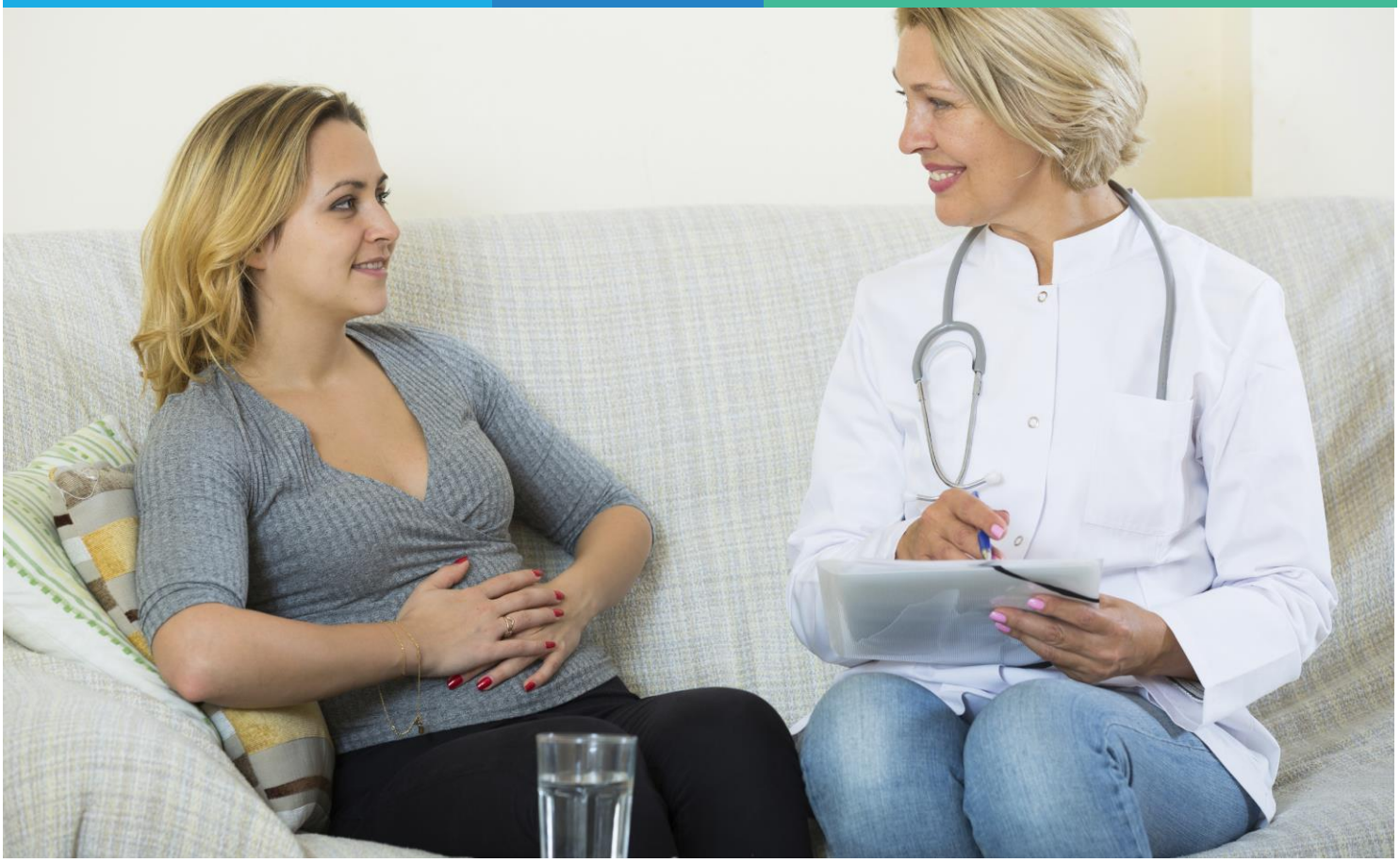
Queen Mary University of London

Insert Trust Logo

Did you know, 1 in 10 people suffer from chronic constipation? To find out more about current treatments we are studying, please read this information sheet.



Chronic Constipation Treatment pathwaY study 3 (CapaCiTY03) is a Waiting List Controlled Trial of Surgical Treatment for Adults with Chronic Constipation

Invitation to participate

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. One of our team will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 15 minutes. We will give you at least a day to make your decision, but you can take as much time as you like. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Please ask us if there is anything that is not clear.

Part 1: About the research

Background

Constipation is a common condition that most people will suffer with at some point in their life. In some people the symptoms can become chronic and severely affect their day to day activities. Chronic constipation is described as someone having symptoms that last for over 6 months and has not responded to simple dietary, lifestyle changes and laxatives. The condition can be very difficult to treat even in specialist centres. Initially patients are offered lifestyle advice and laxatives followed by nurse led treatment like bowel retraining.

Though these treatments are often helpful, in some patients they don't work due to particular structural problems of the pelvic floor for example prolapse of the bowel. An external prolapse of the rectum is when the bowel slides out of anus and an internal prolapse is when the rectum slides in on itself. A number of surgical procedures exist to try and improve these structural problems by hitching the bowel back up inside so it can't slip down. One operation called laparoscopic ventral mesh rectopexy has become the standard of care for treating patients with rectal prolapse. This key-hole operation is described on page 4 under surgical visit.

What is the purpose of the study?

The main aim of this study is to determine how effective laparoscopic ventral mesh rectopexy is in improving symptoms of chronic constipation as well as quality of life. In addition, the cost effectiveness of the surgery, to the NHS, and the patient's experience of the treatment will also be assessed. The study uses a special type of trial design to do this. In contrast to a traditional clinical trial, the design of this trial will mean all patients that take part will have the surgery

Why have I been invited?

You have been asked to take part in this study because you are between the age of 18 and 70, have symptoms of chronic constipation and previous diet, lifestyle changes, laxatives and nurse led treatment have not adequately helped with symptoms of constipation. Your doctor has already recommended

the above surgery (laparoscopic ventral mesh rectopexy) for your ongoing symptoms. The study does not affect this decision or the performance of the surgery itself – rather, we wish to collect information before and after your procedure, this is in addition to routine follow up assessments by your surgeon.

Do I have to take part?
Participation is entirely voluntary. It is up to you to decide if you want to take part or not after you have had time to think about it. We will describe the study and take you through this information sheet. 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 not to take part, or if you withdraw from the study, the standard of care you receive will not be affected.

What will happen to me if I take part?
This research is taking place at approximately 10 specialist NHS centres across the UK over 5 years.

Your participation in this particular study will last for up to 18 months (72 weeks) and will involve 8 visits to the hospital as outlined below. This study is a type of wait list controlled randomised trial, which means we put people into 3 different groups and each group will wait a different time for surgery. The results of those who have had surgery are compared to those who are waiting for surgery. To try to make sure the groups are the same to start with, each patient is put into a waiting list group by chance (randomly). All patients will have to initially wait 4 weeks after their first appointment for surgery to be organised. Patients have a 1 in 3 chance of going to each of the groups:

Group 1: Surgery straight away (4 weeks + 0 weeks wait time)
Group 2: Surgery in 12 weeks (4 weeks + 12 weeks wait time)
Group 3: Surgery in 24 weeks (4 weeks + 24 weeks wait time)

The Participant Flow chart (figure 2, on page 6) shows the complete visit plan and illustrates that your participation in the study will last for 8 visits over 18 months. The visits are described in detail below.

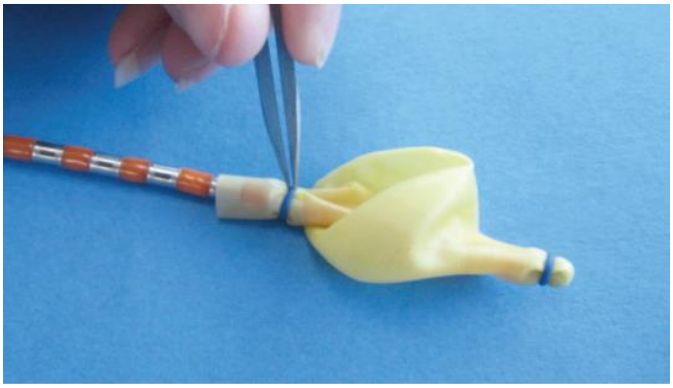
Visit 1: Initially you will have a medical history taken and undergo a physical examination including a brief examination of your front and back passage (if not already performed recently). You will be given questionnaires and a diary to complete.

If not previously performed in the last 12 months, you will need to undergo a number of more precise routine tests outlined below, looking at the structure of the lower bowel and back passage and how it works and whether there are any abnormalities. This may require 1-2 extra visits to the hospital and waiting times of 4-12 weeks, which is the normal NHS waiting time for these tests. We will endeavour to keep wait times to a minimum (average 4 weeks). Two of these tests include X-rays with a very small dose of radiation, equivalent to about 7 months background radiation dose from living in the UK. Because the tests involve radiation, a urine or serum pregnancy test will be requested from women of childbearing potential.

1. Anorectal manometry with sensory testing– this includes insertion of a balloon catheter (see figure 1) into the back passage to measure sensation and contractions and also your ability to push out the balloon.
2. Evacuating proctogram – A mixture of barium paste and soft solids such as oatmeal is inserted into the rectum, following which you will be asked to sit upon a commode and to push the paste out. The barium shows up on X-Ray, and can thus be seen on a fluoroscope, a kind of X-Ray television. A privacy screen will be placed around the commode so no one is directly watching you (only your X-ray).
3. Gut transit study – measures the movement of food through the stomach and intestines. This requires you to swallow 3 gel capsules (size of a normal antibiotic capsule) filled with

markers that will show up on an X-ray. The markers look like white spots or rings in the X-ray pictures, taken 120 hours after swallowing the capsules. You will be required to stop taking laxatives before having this test.

Figure 1: Balloon catheter



The surgical team will assess your results and suitability for surgery and you will then be randomly assigned to one of the three groups.

Surgery visit: The timing of this visit will depend on which of the three groups you have been allocated to. You will undergo a routine admission into hospital without any change to care. The surgeons will be experienced in this type of surgery and have all received expert guidance and training.

The operation will be done under general anaesthetic (whilst you are asleep). It is done using keyhole surgery and takes about one and a half to two and a half hours. It involves a small cut just below the belly button and then two to three further small cuts on the right side of the tummy. The operation pulls the bowel up out of the pelvis using a mesh (sterile piece of netting) stitched in to keep the bowel in place. After the operation you will wake up with a drip in your arm and a catheter (tube) in your bladder (which will normally both be removed by the next morning). Patients often stay 1-2 nights after surgery. You will receive a routine surgical follow up appointment 30 days after surgery to check for any complications.

Assessment Visits 2-6: To fulfil the primary aims of the study, all patients will be assessed at baseline (visit 1) and then every 12 weeks for 4 more assessment visits (at 12, 24, 36 and 48 weeks) i.e. a participation of just less than one year. Depending on which group you have been allocated to, you may have 1 or 2 of these assessment visits before your surgery.

Assessment Visits 7-8: Subsequent visits at 12 week intervals will be required to fulfil the secondary aims of the trial and will help researchers to collect longer-term outcomes of surgery. We are particularly keen to assess patients at 60 and 72 weeks (just under 18 months total involvement) so that every patient has approximately one year post-surgical follow up to measure what the long term benefits of surgery may be.

At all these assessment visits you will be asked to complete a questionnaire booklet and given a diary and journal to complete at home. Each diary will take a couple of minutes to complete at the end of each day for two weeks prior to your assessment visit. The questionnaires should take 10-20 minutes in total to complete. A member of the research team will also ask you about your current health, any complications and medications you are taking. You will be given a journal to record this information in.

You will be given the option to complete the diary and questionnaires either on paper or directly online, using any handheld device or computer. To complete the assessments online, you will be asked to provide your email address and an automatic email reminder will be sent asking you to complete your assessments. You will then either meet with the researcher every 12 weeks or be contacted over the phone to ensure the information is complete, return your booklets and receive support for any complications.

You may also be approached to take part in one to one interviews. This is up to you to decide separately to this part of the study. If you are interested, your contact details will be used by researchers from Kings College London to give you further information and you will be contacted and consented to take part at a later date.

What will I have to do?

If you choose to be part of this study, it is important for you to:

- Attend your visits on the scheduled dates
- Complete your diary, journal and questionnaires. The diary records bowel movements, the journal records laxative use, new medications which are taken, visits to the doctor and costs of treatments. The questionnaires will ask you about your health and wellbeing.
- Follow the instructions you receive during the visits
- Follow routine post-operative care instructions

Expenses and Payments

If you decide to take part you will be reimbursed with £60 to help cover the expenses incurred with the extra visits to hospital (on top of your routine surgical and follow up visits). This will be given out over the course of the study (e.g. £20 on completion of visit 1, visit 6 and visit 8).

What are the possible disadvantages, risks and side effects of taking part?

The study involves procedures that are done routinely in normal care and have been done in specialist centres throughout the UK and internationally. Two of the routine tests use X-rays. We are all exposed daily to 'Background Radiation' that comes from natural sources all around us. The X-rays you could receive during the test are equal to less than 7 months of background radiation and considered minimal risk.

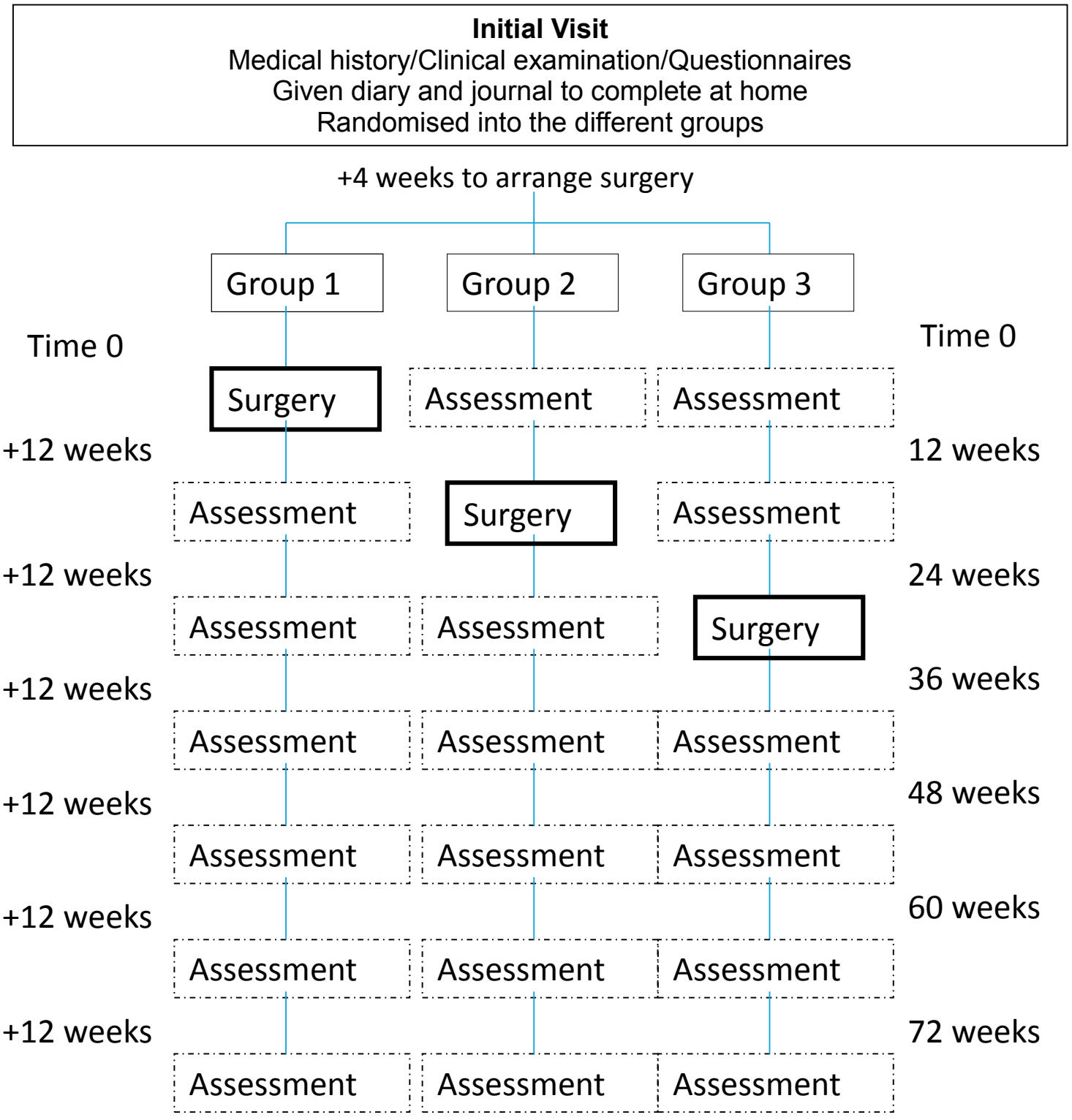
As there will be use of X-rays, it is very important to let the research team know if there is any chance that you are pregnant. For this reason you may be asked to perform a pregnancy test and will be excluded from the study if you are pregnant or trying to get pregnant. Women entering the study will also be asked to use proven methods to prevent pregnancy throughout the course of the study.

Women must advise the research team if they become pregnant or would like to start trying to become pregnant. If this happens you will be withdrawn from the study treatment but may continue to complete diaries and questionnaires if you like.

The surgical risks will be explained prior to surgery and you will be asked to sign a separate NHS consent form for surgery. Some of the known but rarely occurring risks of this type of surgery include;

- Bleeding
- Vaginal or rectal injury requiring repair
- Infection (<3%)
- Urinary retention (<10%) or worsening of urinary incontinence
- Mesh erosion (where the mesh wears away surrounding tissue) (<3%)
- Sexual dysfunction in men (rare)
- Severe constipation (rare)
- Pain during sexual intercourse (uncommon and usually gets better with time)
- Infection of the sacrum (inflammation of one of the discs of the spine)(rare)

Figure 2: Participant Flow chart



What are the possible benefits of taking part?
We cannot promise the study will help your constipation. However, we hope there may be improvements and the information we get from this study will help inform future treatment of people with chronic constipation.

What happens when the research study stops?
If you require further treatment you will return to being looked after in the regular clinic. With your permission, we would like to be able to use the data collected in this study for future research of a similar nature. All future research will require ethical review and approval and your data will remain confidential.

What if there is a problem?
Any complaint about the way you have been dealt with during the clinical trial or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?
If new information becomes available about the treatments being studied or the way in which we are planning to conduct the study, you will be notified so that you can re-consider your involvement. This is very unlikely to occur but if it does the researcher will discuss this with you and ask you to sign a document confirming the changes were explained and you have agreed to either continue or withdraw and return to routine care.

What will happen if I don't want to carry on with the study?
You are free to drop out of this study at any time by notifying the study nurse or doctor and without having to give a reason. This would not affect the care you receive. If you withdraw from the study any information collected up to that point will still be used but no further information will be collected. You may also be given the option to withdraw from treatment but continue to complete questionnaires and diaries if you wish. If you become unable to complete the study you will be withdrawn but the data collected up until then will still be used.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Please insert local investigator contact details here). If you remain unhappy and wish to complain you should contact the Patient Advice and Liaison Service (PALS) <insert local Pals contact here>

We do not expect you to suffer any serious harm or injury as a result of this research. The risks of taking part in the trial are considered low over and above standard surgical risks and the risk of the surgery itself is small. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action against the sponsor Queen Mary, University of London, but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?
If you consent to take part in this study, Doctors, nurses and other personnel involved in the study may need access to your medical records and test results. Your contact details (e.g. email address and/or phone number) and data relevant to your involvement in the study will need to be accessed by the coordinating centre at Queen Mary University

London e.g. in order to arrange your follow up visits and Kings College London to arrange your interview.

The records obtained while you are in this study will remain strictly confidential at all times. The information will be held securely on paper and electronically under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or Sponsor, who is not involved in the trial. You will be allocated a unique participant number, consisting of the study number, a hospital code and a number given in order of enrolment. This code will be used to identify you on all trial forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

In line with the regulations, at the end of the study your data will be securely archived for a minimum of 20 years. Arrangements for confidential destruction will then be made.

Will my GP be informed of my involvement?
Your GP, and other doctors treating you, will be notified that you are taking part in this study.

What will happen to the results of the research study?
The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor after the study has ended. A lay summary of the results will also be provided to the study participants at the end of the study and published on the bowel and cancer website at www.bowelcancerresearch.org

Who is organising and funding the research?
The sponsor, who is responsible overall for this study is Queen Mary, University of London. The research is being funded by the Department of Health through the National Institute for Health Research (NIHR).

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your safety, rights and wellbeing. This study has been reviewed and approved by London City and East Research Ethics Committee.

Further information and contact details
You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved.

Principal Investigator

Name *add name*
Tel. Number: *add Tel. number*

Your Research Nurse
Specialist Nurse
Research Fellow *delete as appropriate*

Name *add name*
Tel. Number: *add Tel. number*