

Patient Information Summary Sheet

Streamline C:

Streamlining Staging of Colorectal Cancer with Whole Body MRI

You are being invited to participate in this trial because your doctor thinks it is possible you may have colorectal cancer. Alternatively, your doctor may already have told you that you do have colorectal cancer.

The reason for doing this trial is to investigate whether whole body magnetic resonance imaging (WB-MRI) is better or quicker at staging newly diagnosed cancer than the standard tests currently used. Cancer staging describes how far a cancer has spread from the main tumour to other parts of the body. Correct staging is important since doctors use this information to decide on treatment. We also want to find out how the cost of using WB-MRI compares to using just the standard tests.

WB-MRI is a scanning technique which can image the whole body in about 1 hour. MRI scanning has been around for a while and is already commonly performed in hospitals. However, using MRI to look at the whole body in one go is quite new. The main advantage of WB-MRI may be for those patients with newly diagnosed or suspected cancer. Currently patients often undergo several different scans and tests which may be time consuming and involve multiple visits to the hospital. We want to see if one WB-MRI could replace the multiple scans and tests. As noted above, we understand you may not have been diagnosed with colorectal cancer, but because your doctor has requested other tests we would still like to invite you to take part.

It is up to you to decide whether or not you want to take part. We will describe the trial and go through the full information sheet with you. We will also give you a copy of this information sheet to keep. If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you take part you will then have all the usual scans and tests your doctor would normally request even if you were not taking part in the trial. As a result of taking part in the trial, you will also have one extra WB-MRI scan. This may require you to make an extra visit to the hospital, and may take place at a different hospital from where the rest of your tests are being done. We will pay your travel expenses to attend for the WB-MRI. As part of the trial you will also be asked to complete short questionnaires about how you feel (quality of life) and record your use of NHS and GP services over the next 12 months (diary). Another part of the trial is to see how patients like you feel about the whole investigation process, including your views, preferences and the importance you place on a number of different experiences related to staging. We will do this by asking you to complete a questionnaire. Participation in this is optional.

If you are interested in taking part in this trial, you should read the rest of this information sheet. Please discuss the trial with your family, carers and others and feel free to ask if there is anything that is not clear or you would like more information about. Take time to decide whether or not you wish to take part.

Thank you.

Patient Information Sheet

Streamline C:

Streamlining Staging of Colorectal Cancer with Whole Body MRI

An independent multi-centre prospective cohort trial comparing the staging accuracy of early WB MRI with standard pathways in newly diagnosed Colorectal cancer

Introduction

We would like to invite you to take part in a research trial. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the trial if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been invited?

Your doctor thinks it is possible you may have colorectal cancer. Alternatively, your doctor may already have told you that you do have colorectal cancer. You have been invited to take part in this trial because you now need to have tests and scans that will provide your doctors with the information they need to correctly diagnose and treat you.

If your doctor is not sure whether or not you have colorectal cancer, these tests and investigations should provide an answer to this question. If it turns out you do not have colorectal cancer then we would not need to collect any more information about you after that point.

In total, 360 patients with colorectal cancer will be enrolled in this trial from around 18 hospitals across the UK.

What is the purpose of the trial?

The reason for doing this trial is to investigate whether whole body magnetic resonance imaging (WB-MRI) is better or quicker at staging newly diagnosed cancer than the standard tests currently used. Cancer staging describes how far a cancer has spread from the main tumour to other parts of the body. Correct staging is important since doctors use this information to decide on treatment. We also want to find out how the cost of using WB-MRI compares to using just the standard tests.

WB-MRI is a scanning technique which can image the whole body in about 1 hour. MRI scanning has been around for a while and is already commonly performed in hospitals. However, using MRI to look at the whole body in one go is quite new. The main advantage of WB-MRI may be for those patients with newly diagnosed or suspected cancer. Currently patients often undergo several different scans and tests

which may be time consuming and involve multiple visits to the hospital. We want to see if one WB-MRI could replace the multiple scans and tests. As noted above, we understand you may not have been diagnosed with colorectal cancer, but because your doctor has requested other tests we would still like to invite you to take part.

Do I have to take part?

It is up to you to decide whether or not you want to take part. We will describe the trial and go through this information sheet with you. We will also give you a copy of this information sheet to keep. If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part, you will have all the usual scans and tests your doctor would normally request even if you were not taking part in the trial. As a result of taking part in the trial, you will also have a WB-MRI scan. The WB-MRI scan is not something you would have if you were not taking part in the trial. This may require you to make an extra visit to the hospital, and may take place at a different hospital from where the rest of your tests are being done.

MRI is a safe test and does not use X-ray radiation. The scan takes about an hour, although you will be able to have breaks during this time if you need. You will lie on your back on the scanner table. The scanner itself is like a large ring. The scanner can be quite noisy and you will be provided with headphones or earplugs. You will be able to talk to the radiographers performing your scan at all times. The scan will require you to hold your breath from time to time. You will be provided with an emergency button to stop the scan if you are worried in any way.

We will need to give you a small injection of contrast dye during the scan so we will place a small needle into an arm vein. There are no after effects from the scan and you can go straight back to your normal daily activity afterwards.

The WB-MRI scan will not delay any treatment you may need. It will usually take place within 3 weeks of booking, and often sooner than this. You will also undergo all the usual tests and scans your doctor would normally request - the WB-MRI is an additional investigation and will not interfere with your standard care. Although the WB-MRI is being carried out for the purposes of this trial, your doctors will use all your test results (including the WB-MRI) before they make their final decision on how best to treat you.

It is important that by taking part in the trial your treatment is not adversely delayed. If you agree to take part in the trial but we are not able to offer you an MRI appointment within a reasonable time due to capacity issues, your doctor may decide it would be better for you not to take part rather than delay things.

We will follow your care for 12 months to collect information about the scans and investigations you have, the treatment you receive, and the results of any surgery and biopsies. You won't have to make any extra visits to hospital during this time, other than the one for the WB-MRI. However, we will ask you to fill in a diary and send this in once every 3 months. We'd like you to use the diary to write down things like any

medication you are taking, and how many times you visited the hospital or saw your GP. This will help us work out the overall costs of NHS care. This shouldn't take more than a few minutes each week. We will also ask you to complete a short questionnaire about your health and how you are feeling. We will provide pre-paid reply envelopes to help you send these back and will remind you when you should send them in.

Patient Preference Questionnaire

Another part of the trial is to see how patients like you feel about the whole investigation process, including your views, preferences and the importance you place on a number of different experiences related to staging. We will do this by asking you to complete a questionnaire which will be posted to you immediately after you consent to the trial. We will give the questionnaire to about 50 patients. We will ask you if you are willing to take part in this section of the trial, but you can just have the WB-MRI if you prefer.

If you agree to take part in the questionnaire section of the trial, we will send you a paper questionnaire after you consent. The questionnaire will ask for your preferences between two different types of scans and will ask you to choose which one you would prefer to experience. It will also ask a bit about how you are feeling in general and some general background detail on you. Again, you do not have to answer any questions you do not want to. With your permission we may compare your answers with the other clinical information we collect as part of the trial. The questionnaire should not take you more than thirty minutes to fill in.

Expenses and payments

Travel expenses are available to cover the cost of travelling to the hospital for the WB-MRI. If you wish to claim for travel expenses, make sure you keep receipts for your journeys. You will be provided with a travel expense form along with detailed instructions about how to claim this back once you have signed the consent form for this trial. If you agree to take part in the questionnaire section of the trial you will be reimbursed for your time. You will receive £20 for completing the questionnaire.

What will I have to do?

If you are interested in taking part, we may ask you to sign the consent form today so that we can get a WB-MRI scan appointment booked for you as quickly as possible. We know that this does not give you much time to think about whether or not you want to take part, but you can always change your mind. If you sign the consent form and then change your mind about taking part, it is not a problem - you just need to let us know. We will give you a number to call if this is the case. You can ask the hospital to call you if you prefer.

We record your consent at the start of the trial by asking you to sign the consent form. However, consent is an ongoing process. Your continuing consent to take part in this study is demonstrated when you carry out tasks related to the trial (e.g. completing patient diaries), and if you do not tell us you no longer want to be involved. If anything happened that left you unable to tell us whether or not you still wanted to be in the trial (if you "lost capacity"), we would still wish to continue to collect information about your health and care. This information would be very important to make sure we draw the

right conclusions from the trial. If you lost capacity, we would not expect you to do any more trial related tasks. Furthermore, before deciding it would be OK to continue to collect information about you, your care team at the hospital would take into account anything you may have said before hand about taking part in the study. They would also talk to your family or others close to you to make sure they were not aware of any reason why you would not have wanted this to happen.

You will need to show up for your WB-MRI scan appointment, or let us know if you cannot make it, or if you have changed your mind about taking part in the trial.

We will send you a short diary which you should fill in each week and return every 3 months for a year.

If you take part in this trial you are still free to take part in any other trial your doctor may tell you about.

What is the procedure that is being tested?

We are testing whole body MRI to see how it compares to standard tests and investigations in being able to detect cancer spread.

What are the alternatives for diagnosis or treatment?

As noted above, there are other scans and tests used in routine clinical care. You will still undergo all the tests and investigations your doctor would normally want you to. The WB-MRI is in addition to these tests and not instead of them. Your doctors will be able to use all the information when they decide your treatment.

What are the possible disadvantages and risks of taking part?

There are very few disadvantages of taking part in the trial. You will have to attend an extra appointment at the hospital for the WB-MRI scan, but the scan should take a maximum of 1 hour and we will reimburse you for your extra travel expense.

Although MRI is regarded as a completely safe imaging method, we do not know for sure whether MRI is absolutely risk free in the early stages of pregnancy. Therefore, pregnant women should not to take part in the trial. Please tell you doctor if you think you may be pregnant.

It is possible the WB-MRI may pick up potential problems that your standard investigations do not. If it does happen, your doctor will be told about it so he or she can make decisions about how you need to be treated as a result. You may have to have more tests to investigate these new findings on the WB-MRI. Some of these tests may involve x-ray radiation or invasive biopsies to obtain tissue. However these additional tests will only be performed if your doctor requests them and thinks you need them as part of your clinical care. They are not part of the trial. By taking part in the trial you are not consenting to any additional tests other than the WB-MRI scan.

As part of your normal care you may undergo CT scans or PET/CT scans and they carry a possible risk as they involve exposure to radiation. It is important to remember that you would have had these scans in any case as part of your normal care and not

because you agreed to take part in the trial. No additional scans using radiation are performed as part of the trial itself.

What are the side effects of any procedure received when taking part?

MRI is a safe technique that has no harmful side effects. There are certain precautions that we undertake to ensure that the individuals having the MRI scan can do so safely, for example making sure that you do not have any metal in your body e.g. A pace maker, or metal heart valve fitted. We will ask you a set of routine questions before you are allowed to enter the MRI scanner room.

The contrast dye we inject into your vein (gadolinium) during your routine MRI has been used in day to day practice for a long time and is very safe. Allergy to the gadolinium contrast is possible but very rare. Mild reactions such as nausea or a temporary rash, occur in less than 3 out of every 100 patients and more serious reactions are much less common than this.

What are the possible benefits of taking part?

It is possible WB-MRI may provide doctors with extra useful information about your condition which could help in your treatment, but we cannot guarantee this. Even if you do not benefit directly from taking part in the trial, the information we get as a result of your participation will help improve the care of people with colorectal cancer.

Will my taking part in the trial be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential.

The Cancer Research UK & University College London Cancer Trials Centre (UCL CTC) will keep confidential details about you, including your name, address, date of birth, and gender, as well as relevant information about your medical care and treatment. All of this information will be stored securely and handled according to data protection guidelines. Your anonymised data may also be used for future research and you will be requested to consent to this.

If you consent to take part in the research, some parts of your medical records and any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor) of the trial, as well as the UCL CTC who are coordinating the trial and other members of the research team. These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

Images from your WB-MRI may be stored on a computer outside of the NHS. These images will be anonymised (they will bear a trial number, and date of birth). The company who will be providing this service is called Biotronics3D. Biotronics3D will store the information securely and will handle your data according to the data protection guidelines. They are used to working with the NHS.

If you decide to take part in the optional patient preferences questionnaire, your anonymised answers will be transferred to Birkbeck, University of London. This is where the researchers who are conducting this part of the trial are based. All the information you give the researchers through your participation in the questionnaire will be held in strict confidence. The researchers at Birkbeck will also be given access to relevant information about your medical care and treatment. Only the research team will have access to it. Only group information will be given in any publication from the trial; it would not be possible to identify you individually in any publication. Data collected as part of this research will be retained for 10 years in line with Birkbeck, University of London's records management policy. Any completed questionnaire (which will be anonymised) will be retained in line with this policy in a locked room and will be shredded at the end of this time period.

The organisations listed above will keep information about you confidential. Your name will not be used in any reports about the trial and all data is stored in accordance with the principle of the Data Protection Act 1998. However, your hospital doctor may tell your GP about the findings on the WB-MRI scan.

What if relevant new information becomes available?

It is very unlikely that any new information will come to light that would affect your participation in this trial. However, if it does happen, your research doctor will tell you and discuss whether you should continue in the trial. If this happens before you have had your WB-MRI, then new information could affect whether or not you should go ahead with this. However, if you have already had your WB-MRI scan, then new information would not affect your care or treatment in any way.

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

You can withdraw from the trial but we would like to keep in contact with you through your doctor so that we know about your progress. Information already collected may still be used.

What if there is a problem?

Every care will be taken in the course of this trial. However in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation.

After discussing with your research doctor, please make the claim in writing to Prof Stuart Taylor. He is the Chief Investigator for this trial and is based at UCLH. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the research, the normal National Health Service complaints mechanisms are available to you. Please ask your research doctors if you would like more information on this.

Details can also be obtained from the Department of Health website:
<http://www.dh.gov.uk>.

What will happen to the results of the research trial?

After the trial is complete we will aim to analyse the results, write them up in medical journals and hopefully change to way we stage colorectal cancer. Your doctor will told about the results of the trial if you wish to contact them once the results have been published.

Who is organising and funding the research?

The trial is funded by National Institute for Health Research Health Technology Assessment (NIHR HTA) and is being run by Cancer Research UK & UCL Cancer Trials Centre, London.

Who has reviewed the trial?

All proposals for research are reviewed by an ethics committee before they can proceed. This proposal was reviewed by the Health Technology Assessment (HTA) and the London- Camden and Islington Research Ethics Committee and both have given their approval. The local Research & Development department for your hospital has also given approval.

Thank You

Further information

Macmillan Cancer Support are an independent organisation providing support and counselling to help people live with cancer. They can be contacted at:

<http://www.macmillan.org.uk/Aboutus/ContactUs/ContactUs.aspx>

Cancerhelp (Cancer Research UK) who provide all aspects of information for people with cancer. Their contact details are:

Tel: 020 7061 8355

Freephone: 0808 800 1234

Or visit their website at <http://www.cancerhelp.org.uk>

Useful contacts:

Local Contacts:

Your doctor Tel:

Your nurse Tel:

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