

Rec Ref:

IRAS ID: 345225

Volunteer Participant Information Sheet (VPIS)

Part 1

Study Title: Assessing the use of artificial intelligence in rectal magnetic resonance imaging.

Chief Investigator: Dr Anita Wale, Consultant Radiologist

Invitation to participate in the above study:

We would like to invite you to take part in a research study part of a MSc Clinical Science (Medical Physics) student project along the workstream of the Imaging Research Group with the hope that it will benefit patients referred for a pelvis (Magnetic Resonance Imaging) to assess their rectum. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully and discuss it with others if you wish. **We will go through the information sheet with you and answer any questions you have.** We'd suggest this should take about 35 minutes.

Part 1 of the PIS 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. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

This study aims to assess an Artificial Intelligence (AI) technique that can make MR images clearer and more detailed, whilst also able to complete the scan in a much shorter time. This AI technique has already been established at numerous NHS trusts and is a CE marked product, however, requires validation in MRI rectum scans at St George's Hospital.

MRI scans of the rectum are only performed for patients who are diagnosed with rectal cancer. These scans have been proven to select patients for the right treatment. Patients with more advanced disease need a tumour shrinkage for successful surgery. Therefore all patients with rectal cancer will have an MRI scan at diagnosis and patients who need additional treatment before surgery have another MRI scan to show that this has worked and helps plan their surgery. As a result all patients having a rectal MRI scan irrespective of where on their cancer pathway they are (diagnosis or post downstaging) will be invited to take part.

Why have I been invited?

You have been invited to take part in this study as a healthy control for a pelvis MRI scan. If you would like to take the opportunity and enrol in this study, you will be 1 of approximately 15 other healthy volunteer participants.

Do I have to take part?

Your involvement in this study is completely voluntary and it's only up to you to decide. Prior to your involvement, we will describe the study and go through this information sheet. If you would like to be involved in this study, you will be given this information sheet to keep and asked to sign a consent form. You are still free to withdraw at any time, even if you had initially accepted the invitation for this study. You will never need to give a reason for withdrawing, nor will you be asked for one.

What will happen to me if I take part?

If you decide to enrol in this study, you will undergo an MRI scan that will last no longer than 1 hour. These scans will include the standard imaging protocol, as well as a protocol that uses the AI technique that can make images clearer, scans shorter or both. Your role on the study will only last for the 1 hour that you volunteer for your scan. The session may take up to 1 hour because different imaging parameters will be tested during the duration of your scans, which means some sequences may be repeated various times. Details that can be used to identify you will not be registered on the scanner, and instead will be pseudo-anonymised. This will ensure that you cannot be identified by anyone who has access to the hospital computer network.

Following your scan, the images will be reviewed by a radiologist, a specialist doctor who usually reads the MRI scan images and who will also assess if the additional scans with the AI technique are improved. If this is the case, then the AI enabled scans will be tested on patients with the hope that they will eventually replace the current clinical protocol.

All images will be stored on the hospital's secure computer network for up to 10 years. If you wish for the images acquired as part of this study to be deleted, please contact the research team on **0208 266 6244** or email us at mrphysics@stgeorges.nhs.uk. If any images are deemed useful for publication e.g. in a scientific journal, all images will be fully anonymised. Therefore, you will not be able to be identified from the images.

This study is expected to last up to a year.

Expenses and payments

Unfortunately, there are no expenses or reimbursements for participating in this study.

What do I have to do?

If you choose to participate in this study, please read this Volunteer Participant Information Sheet (VPIS) in its entirety and complete the consent form. You will also have to complete the 'MRI Screening Questionnaire' and change into a patient gown; however, this is also necessary for all routine MRI scans.

You will not be excluded from this study if you are/have been involved in any other study but may not be able to participate if you have an implant or are pregnant. If you do have an implant of any sort, or may be pregnant, it is important to make a radiographer aware of this before your scan.

Your participation in this study will only require you to spend up to 1 hour of scanning. You will not be asked to do anything apart from continuing to remain still and breathing normally.

Once your scan is over, you won't have to do anything further as part of your participation in the study. You will be informed if incidental findings are shared with the GP.

What are the possible disadvantages and risks of taking part?

As you will be spending up to 1 hour in the scanner, please consider whether you are a suitable candidate. 1 hour inside the scanner should not be underestimated if you suffer from claustrophobia or anxiety.

Your images will be reviewed by a radiologist, a specialised doctor who can analyse MRI images. In the event of an incidental finding (something unexpected discovered during your MRI that was done for another reason), your GP will be contacted and informed. You will be informed that your GP has been contacted regarding an incidental finding from your MRI. You should be made aware that discovery of an incidental finding may influence current or future life insurance or medical insurance policies (or equivalent).

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

There is no added risk when using the AI tool compared to a normal MRI scan. Though MRI is a purely diagnostic tool and does not provide any treatment, we still must consider a number of factors. This includes loud acoustic noises that are generated by the scanner, for which you are provided ear plugs and headphones. Additionally, a small amount of heating can be induced within the human body, however, this is normal for routine MRI and there is no added risk of this from the additional sequences that use AI. It should be made clear that radiographers are trained to monitor and limit any heating that is induced by the MRI scanner.

It is highly unlikely that any side-effect or adverse effect would result from MRI but if you would like to discuss the safety of MRI or wish to report any adverse effect to us, please contact us on **0208 266 6244** or email us at mrphysics@stgeorges.nhs.uk.

Radiation Risk

There is no ionising radiation used in routine MRI or as part of this study.

What are the possible benefits of taking part?

The potential benefit of taking part in this study is that you get to experience what it is like to undergo an MRI scan, if you have not already had one yet.

Furthermore, participation in this study means that if the scan using the AI technique is found to be successful, it can be implemented routinely sooner, which is expected to improve both patient and staff outcomes.

What if there is a problem?

If there is a problem during your scan, you can halt it at any time using the patient buzzer that is handed to you during your MRI.

Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

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?

It is unlikely that any new information about the AI technique will affect you.

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

You may wish to exit from this study at any point, even during scanning. If you do wish not to carry on with the study whilst you are in the MRI scanner, press the patient buzzer that you are provided with, and a radiographer will assist you exiting the scanner.

With your permission, we would like to keep any images that have been acquired up to the point of your withdrawal for use in scientific publications. Furthermore, the findings of this study may lead to further research questions. If so, we would be keen to use your imaging in the future. No images would contain information that could be used to identify you, and we understand if you choose not to give permission for this. You will also not need to give or feel pressured to explain your decision.

What if there is a problem?

If there is an issue that relates to the MRI scan procedure that you underwent, please contact the MRI department on **0208 725 3037** so that radiographers and, if necessary, MRI physicists can investigate further. If it was found that an incident did occur, then this will be reported locally, via a DATIX, that aims to learn and prevent the incident from occurring again.

Complaints:

If there is any issue you would like to highlight or a complaint you wish to make about your experience on the study, then please report this to one of the researchers, (Zach Pang, Khaliesah Bolhassan) who will do their best to answer your questions or concerns, on 0208 266 6244 or email us at mrphysics@stgeores.nhs.uk .

If the issue or complaint you wish to raise is about the care you received from a member of staff, unrelated to the study, then please report this to the MRI department on 0208 725 3037.

If you do not wish to raise a complaint through either of these channels, then a complaint can be made via the normal National Health Service complaints mechanism available/patient advice and liaison services (PALS) via email (pals@stgeorges.nhs.uk) or by phone (02087252453), which is open 9am – 5pm, Monday – Friday.

All complaints raised will be handled with the utmost care and understanding.

Harm:

St George's University Hospitals NHS Foundation Trust sponsored research:

St Georges University Hospitals NHS Foundation Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the sponsor (St Georges University Hospitals NHS Foundation Trust), but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

Will my taking part in the study be kept confidential?

Your involvement in this study will be always kept confidential. The images that we collect will be stored on St George's Hospital's secure network for up to 10 years and will be psuedo-anonymised (replacing identifiable information like names and dates of birth with pseudonyms, and keeping a key to re-identify the data if needed) so that you cannot be identified.

Any record of your participation and the data we collect from your images will be coded and/or anonymised so you will not be able to be identified. Any electronic copies will be secured on St George's Hospital's secure network whilst any hard copies will be secured on site.

Furthermore, your data will only be accessed by researchers on this project with your data being retained only for as long as it is needed for the study. This also means that the images can be deleted once the study has finished.

How will we use information about you?

Information that can be used to identify you will be kept confidential and will never be published. Information about you may need to be accessed in the event that an incidental finding occurs and we need to notify your GP. Relevant sections of a participant's medical notes and personal data collected during the study may be looked at by responsible individuals from St George's University Hospitals NHS Foundation Trust (SGHFT), the NHS Trust or from regulatory authorities.

Additionally, we will also need to use your height and weight as the scanner requires this to calculate safety parameters for your scan.

In the case of an incidental finding, responsible individuals from St George's University Hospitals NHS Foundation Trust (SGHFT) will need to access your name, NHS number, and GP information in order to inform your GP.

People who are not involved with this research study will not be able to see information that could be used to identify you. Any of your information that we keep will be safe and secure.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we would like to keep your images and information about you that we already have. Your images will be stored for up to 10 years. If you do not wish for your MR images, acquired as part of this study, to be used or you wish for your images to be deleted from St George's Hospital's secure network, please contact the research team on **0208 266 6244** or email us at mrphysics@stgeorges.nhs.uk. so that this can be arranged.

Where can you find out more about how your information is used?

You can find out more about how we use your information
[<https://www.stgeorges.nhs.uk/education-and-research/research/research-privacy-notice/>]

For general information on how the NHS uses research data please visit
<https://www.hra.nhs.uk/information-about-patients/>

What will happen to the results of the research study?

It is intended for the results of the research study to be published as an MSc thesis, as well as published in peer-reviewed scientific journals and/or at international conferences.

If you wish to see these, please let us know and we can make them available to you when they are complete.

The research and data collected will not result in a discovery of commercial value.

Who is organising and funding the research?

This study is being sponsored by St George's Hospital NHS Foundation Trust. No one in this organisation, nor the organisation itself will earn an income from this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favorable opinion by St George's Research Ethics Committee.

COVID-19

If the protocol does not require any attendance at site, then remove this section. Otherwise, it must be completed even if the study visits are integrated with the routine clinical follow-up.

As you are most likely aware, due to the outbreak of Covid-19 (Coronavirus), St Georges, like other hospitals, is treating Covid-19 patients. We are taking extra steps to ensure both staff and patients are kept safe at all times and to prevent any further spread.

We would like to reassure you that we are taking every step possible to ensure your visit is as safe as possible, as part of this you will be asked to follow our Hospital policy on social distancing and PPE whilst you are here for your visit.

Staff will be adhering to strict cleanliness guidelines and, in some cases, this may mean full PPE.

Please attend for the appointment on your own if at all possible. Do not bring any children or relatives. Exceptions to this are official Carers or a Parent / Guardian of a Paediatric Patient.

Please don't attend if you:

- 1) Have been informed that you are in a vulnerable group and should not attend hospital (unless specifically instructed by your doctor that the scan is needed)
- 2) Have a household member, or are yourself, currently experiencing any COVID-19 symptoms

Then you must stay at home and please contact us to let us know so we can postpone your appointment. If you feel your appointment is no longer needed, please let us know.

Further Note:

Routine medical appointments are an exception to social isolation rules. Unless you have received a shielding letter or are currently self-isolating due to COVID-19 exposure, you are permitted to travel to your appointment.

If you have concerns, please don't hesitate to contact us (see below for details)

Further Information and Contact Details

If you have any questions or concerns about this study, please contact one of the researchers (Zach Pang & Khaliesah Bolhassan) on 0208 266 6244. Alternatively, the researchers can be emailed via mrphysics@stgeorges.nhs.uk

The organisation's Data Protection Officer (Nick Murphy-O'Kane) can also be contacted via data.protection@stgeorges.nhs.uk.