STARBEAM-X: Dynamic susceptibility contrast MRI Perfusion assessment of brain metastases: baseline characteristics and the study of pattern of perfusion change in suspected radionecrosis post-stereotactic radiosurgery

Thank you for considering taking part in our study. It is important for you to understand why this research is being done and what it means for you. Please take time to read the following information leaflet carefully and decide whether or not you would like to take part. Please feel free to ask us at any point if there is anything that is not clear or if you need more information, our team will be more than happy to answer any questions you have.

What is the purpose of this study?

The purpose of this study is to use an additional type of picture on the MRI scanner to look into the way brain tumours (cancer that has spread to a part of the brain) behave. In particular, we are interested in using this picture to help us work out which patients develop radiotherapy damage after their treatment.

We are very much hoping that the understanding that we develop in this study will lead to a larger study in future to improve the information MRI scans can yield in secondary brain tumours.

WHO HAS DESIGNED THE STUDY?

Dr Joanne Lewis and Dr Caroline Dobeson

Dr Lewis is the Joint Principal Investigator in association with Dr Dobeson (who is undertaking this study as part of a clinical research fellowship) and we both work at Northern Centre for Cancer Care at the Freeman Hospital. We are both Oncologists with a special interest in research in secondary brain tumours.

Why have I been asked to take part?

You have been asked to take part in this study as you have a tumour in the brain that would be suitable for treatment with radiotherapy. Any patient who has radiotherapy is at risk of developing radiotherapy-related damage and we would like to perform an extra MRI scan picture to see if this helps us identify any damage when we compare these scans with ones you have in the future.

What will happen to me if I agree to take part?

If you agree to take part, we will ask you to either sign a consent form or give verbal telephone consent. During the verbal consent process, we will fully explain the study to you including the possible risks of participation and as much time as you require to discuss any concerns or questions you have. This will be fully recorded in your medical notes and will be followed up with written consent whenever possible. When you attend for your radiotherapy planning MRI scan, our radiographers will know to take an extra picture whilst you're having your scan. This will mean an additional 5 minutes lying down in the MRI scanner.

If you consent to take part in the study, we will also collect some information in relation to your previous cancer treatment from your hospital records. All of the information that is collected will be kept anonymous and securely stored by the research team working within this study.

Once you have undergone your MRI scan and completed radiotherapy, you will continue to have regular MRI scans under the care of your oncology team. For a two year period after your treatment, we will record the results of any further MRI scans that you have to assess how you have responded to radiotherapy. We may use your original MRI scans to help us in making decisions about what your future scans might show, particularly if there is a concern that you may have developed radiotherapy damage.

Do I have to agree to take part?

No. It is entirely up to you whether or not you want to take part. You can keep this information leaflet and ask our study team questions at any point. If you do decide to continue to take part you will be asked to sign a form / confirm verbally giving your consent for this. You are free to withdraw from the study at any time without giving a reason and your data will not be used. At no point will your decision affect the standard of care you receive now or in the future.

What are the possible advantages of taking part?

By taking part, you will be helping us to gather more information about how tumours in the brain respond to radiotherapy and who is at risk of developing radiotherapy damage. This could help guide our radiotherapy treatments in the future and improve patient care.

What are the possible disadvantages or risks of taking part?

MRI scanners don't use radiation, so you will not experience any radiation exposure from extra time in the scanner. Some people do find MRI scanning difficult to undergo because of difficulty in small, enclosed spaces and additional time lying in the scanner could cause some people distress.

Who will know that I am taking part in this study?

All the information we collect during the course of the research will be kept confidential and there are strict laws that ensure your privacy at every stage. Only members of the research team will have access to your information.

During the study, there may be checks performed by the hospital to ensure we are keeping all of your information anonymous and in a secure location.

Will my taking part in this study be kept confidential?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential, and will be held securely in accordance with the Data Protection Act 1998. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your:

- NHS number/Trust ID number
- Initials
- Date of birth
- Contact details
- Details on your cancer diagnosis and treatment you have received

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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, and we will stop collecting information about your scans. With your consent we would request permission to use the information we have already collected on your scans.
- If you choose to stop taking part in the study we can assure you this will have no impact on your care with your Oncology team.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- Although it is a rare occurrence a small proportion of patients may lose the capacity to decide they want to continue being involved in the study – if you inform us at the time of consent that in that circumstance you would wish to withdraw future data about you from the study we guarantee we will honour your wishes.

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

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to nuth.starbeam-x@nhs.net or
- by ringing us on 0191 213 8471
- by contacting the Newcastle Hospitals Data Protection Officer (**e-mail:** nuth.dpo@nhs.net)

What will happen if I don't want to carry on taking part in the study?

You can decide at any time not to carry on with this study, but you should continue attending appointments with your consultant and/or GP as part of your routine hospital care. If you do not want us to use the data collected, it will not be used. Your care will not be affected in any way by your withdrawal.

What will happen to the results of the study?

The results of the study will be used to make recommendations on the treatment for patients with brain metastases. We hope to publish the results of this study in scientific journals and present the information at meetings with other medical professionals who treat brain tumours with radiotherapy. You will not be identified in any publication of results of the study.

We will provide a summary of the results for you to read through and will also share this with online patient support groups and relevant charities.

Who is organising and funding the study?

The study is being organised by Dr Joanne Lewis (Consultant Clinical Oncologist) and Dr Caroline Dobeson (Clinical Research Fellow) with the support of the Radiology Department, Radiotherapy Department and the Clinical Trials Unit. The study is kindly being funded by the Newcastle Hospitals Charity.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC) to protect your interests. This study has been reviewed by the Leicester Central Ethics Committee.

What happens if something goes wrong and I wish to complain?

If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions (for contact details – see below). If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454

Email: patient.relations@nuth.nhs.uk

Address: Patient Relations Department

The Newcastle upon Tyne Hospitals NHS Foundation Trust

The Freeman Hospital

Newcastle upon Tyne

NE7 7DN

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 a legal action for compensation from Newcastle Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Newcastle upon Tyne Hospitals NHS Foundation Trust will keep identifiable information about you for 2 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, or should you lose the capacity to give consent whilst participating in the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information contacting **nuth.dpo@nhs.net**

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the study.

If you have any questions or would like any more information, you can contact the study team directly via our e-mail address: Nuth.starbeam-x@nhs.net

Alternatively, you can contact Dr Lewis' secretary (Janice Macdonald) on 0191 213 8471.