Participant Information Sheet: Patient (post surgery)

Title	**2HG MR spectroscopy in Gliomas**
Study Sponsor	University of Edinburgh
Version	2.2
Date	17.07.2023
PI Name	Prof Adam Waldman

We would like to invite you to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study 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.

1. What is the purpose of the study?

Our goal is to improve the ability to determine the type of brain tumours a patient has from a specialist type of MRI scan. This may help doctors to more accurately decide on the best treatment plan.

MRI stands for Magnetic Resonance Imaging. It is a type of scan that uses magnetism to build up a picture of the inside of the body. The scanner is completely safe and carries no risk to you; unlike X-rays and CT scans, it uses no ionising radiation. The standard MRI scan creates pictures of the brain and is used to diagnose the tumour and determine it's size and location in the brain. There is a need for more information diagnose which type of brain tumour you have. A specialist type of MRI scan called MR spectroscopy also gives additional information about the chemical composition of tumours. This study aims to test how well spectroscopy can identify a specific abnormality, called a mutation, in the tumour's DNA that determines how it will behave and respond to treatment.

2. Why have I been chosen?

Your doctor is inviting you to take part in this study as you have a type of brain tumour called a diffuse glioma and will be having follow up MRI scans after your operation.

3. Do I have to take part?

No, it is up to you to decide whether or not to take part. If you choose to take part you will be asked to sign an informed consent form and you will be given a copy to keep, together with this information sheet.

If you do not wish to take part in the study you do not have to give a reason. You will not be disadvantaged in any way, and it will not affect the standard of care you receive. This also applies if you initially decide to take part and then change your mind at a later date.

4. What are the alternatives for treatment?

It is your decision whether you participate in this study or not. If you decide not to go onto this study you will follow the standard care pathway for this type of disease. Your doctor will discuss your options with you.

5. What will happen to me if I take part?

Your doctor will make sure that you are suitable for entry onto the study and give you this information sheet. You will have time to consider whether to participate and an opportunity to ask questions. Once you have decided to take part and signed a consent form, you will then be enrolled onto the study. Participating in this study will not affect the treatment you receive for your glioma.

As part of your standard treatment you will have MRI scans. By taking part in this study you will also be asked to attend one additional research MRI scan which includes spectroscopy. This scan does not feel any different to the standard MRI scan you have as part of your normal treatment, and will last no more than an hour. Before your MRI scan you will need to change into a hospital gown and remove your jewellery and other metallic objects. An MRI is completely painless, but the scanner is very noisy, and you will be given earplugs. When you are ready, you will need to lie down on your back on the machine couch. You have to lie as still as you can, but breathe normally. Your radiographer will explain any instructions beforehand. If you are getting stiff and need to move, tell the radiographers through the intercom. When the scan is complete you should be able to go home.

Your participation in this study will be finished when you complete your research MRI scan.

6. Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. If you consent to take part in the research the people conducting the study will abide by the Data Protection Act 1988, and the rights you have under this Act.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised personnel from your treating centre and authorised personnel from the study team. It may also be looked at by representatives of regulatory authorities and other authorised personnel from your trust, to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site. All data will be stored in a locked room and all electronic data will be stored securely on hospital Trust computers and in anonymised form on university computers.

7. Expenses and payments

We will not pay you for taking part in the study. We anticipate that you may have one extra visit to Royal Infirmary of Edinburgh in addition your routine care if you choose to participate in this research study.

8. What are the other possible disadvantages and risks of taking part?

MRI Risks

The MRI scan is very safe and does not involve any ionising radiation. You will need to let the study team know if you are pregnant or have any tattoos, or metal clips, staples, implants, etc. inserted inside you, which may mean you will not be allowed to have an MRI scan. MRI scanners are also noisy; you will be given ear defenders to protect your ears.

9. What happens if there is a problem?

University of Edinburgh holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that University of Edinburgh is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator, Adam Waldman (adam.waldman@nhs.net) and co-investigator Dr Gerry Thompson (gerard.thompson@nhslothian.scot.nhs.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the University of Edinburgh ACCORD Office.

10. What if relevant new information becomes available?

It is not anticipated that new information from this study will alter your treatment. This study aims to improve scans for patients in the future. If, however, new information which is relevant to you does become available, your consultant will tell you about it and discuss it with you.

11. What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time and you do not have to give a reason. Your future treatment will not be affected and your doctor will discuss this with you. We would like your permission to continue to receive information on your progress. If you decide that we may have no further information from you for the study, we will need to use the data collected up to the time of your withdrawal.

12. What are the possible benefits of taking part?

We do not anticipate that you will benefit directly by taking part in this study.

13. What happens when the research study stops?

Following completion of your scan you will have ended your study participation. We will then be able to analyse the data by comparing the findings on the scan with the tissue that has previously been removed at surgery. When the results of the study are available a summary can be provided to you upon request. If you choose, your tissue and imaging data may used in other future research.

14. Who is organising and funding the research and where was it reviewed?

This is an investigator-led study. The Chief Investigator is Prof Adam Waldman. The research is funded by The Edinburgh Brain Cancer Fund.

15. Who has reviewed the research?

This study has been through a peer review process. A peer review involves the examination of an author's work by other experts in the same field. These referees each return an evaluation of the work which may include suggestions of improvements if necessary. Your local NHS trust has been given approval for the study to take place at your hospital. The study has also been reviewed by a Research Ethics Committee.

16. Who can I contact for further information?

Useful contacts
Your Research Nurses are:
Name:
Email: ……...
Tel: …0131 537 2274…..…

For information about your disease:

The Brain Tumour Charity is the UK's largest dedicated brain tumour charity, committed to fighting brain tumours on all fronts. The charity funds scientific and clinical research into brain tumours and offer support and information to those affected, whilst raising awareness and influencing policy. Website: http://www.thebraintumourcharity.org. Support & Info Line: 0808 800 0004

The Brain Tumour Research Campaign (BTRC) vision is to raise public awareness of the need for brain tumour research and the lack of funding that currently exists by a series of fundraising events and applications for research grants among corporate and medical bodies or trusts. Website: http://www.wayahead-btrc.org/.