Participant Information Sheet

Clinical 2-hydroxyglutarate magnetic resonance spectroscopy in glioma

You are invited to take part in a research study. To help you decide whether or not 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. Contact 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.

What is the purpose of the study?

Our goal is to improve the ability to determine the type of brain tumours a patient has before they have surgery. This may help doctors to more accurately decide on the best treatment plan and guide surgery for future patients.

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 from researchers at the Universities of Edinburgh and Glasgow 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. 20 brain tumour patients will be selected to participate in this study. Potential participants will be selected as suitable for the study by the PI in discussion with members of the patient's clinical team through the weekly neuro-oncology multidisciplinary team meeting.

Why have I been invited to take part?

You have been asked to take part as you have been diagnosed with a glioma, and will be undergoing MRI scans to assess a tumour in your brain, and it is anticipated that you will have surgery or you have already had surgery.

Do I have to take part?

No, it is up to you to decide whether to take part or not. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. If you do not wish to take part in the study, you do not have to give a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen 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 before you have surgery, at your local hospital. 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.

As part of your treatment it is anticipated that you will have surgery (or you have already had surgery) at your local hospital to take tissue from your tumour for diagnosis and remove as much of it as the surgeon feels is safe. As part of your taking part in this study, the surgeon will take some of the 'biopsy' samples from your tumour during the operation. Taking these samples will prolong your operation by about 10 minutes, and will not involve significant extra risk to you. We will run some histological tests, called immunohistochemistry, on the samples that your surgeon removes. These tests will help us determine the presence or abundance of specific proteins and molecules present in the tumour tissue. Your participation in this study will be finished when your surgery is completed.

Is there anything I need to do or avoid?

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.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

This study will add on additional time to the standard-of-care MRI scanning time (up to 30 minutes). Your GP/healthcare professional will be made aware of your participation in this study (with your consent) and they will receive any incidental findings that may be found during the imaging protocol.

What if there are any problems?

If you have a concern about any aspect of this study please contact Professor Adam Waldman (adam.waldman@ed.ac.uk) who will do their best to answer your questions.

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.

In the unlikely 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 a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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.

What happens when the study is finished?

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.

Imaging and tissue data will be pseudo-anonymised (and transferred to University of Edinburgh servers within Edinburgh Imaging that are only given access to certain members of the research team by employees of Edinburgh Imaging IT. Pseudo-anonymisation of data is the processing of data that makes it unidentifiable to a specific person, by removing information such as name, date of birth, etc. All data will be kept within NHS Lothian and linked anonymised prior to being analysed. Linked anonymisation is a data processing step that uses a random linking identifier (such as 'P-01') to match

pseudo-anonymised data to the personal data. This linking identifier is only accessible by authorised members of the research and clinical team. All data will be password protected and only accessible to appropriate members of the research team. All data linking information will be kept in a locked filing cabinet by the Chief Investigator in their secured and locked office in a pass protected region. All data will be kept for 3 years, after which it will be destroyed by University of Edinburgh-approved methods. All paper files will be kept in the locked filing cabinets in the Chief Investigator's locked office in a pass-protected area of the Royal Infirmary of Edinburgh for the same period of time and destroyed fully.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

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

We will collect your Community Health Index (CHI) number or hospital number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number or hospital number is being collected to link your treatment data to the anonymized imaging and tissue data. People in the research team who are not a part of the clinical care team and who do not need to know your CHI number will not have access to this number.

People who do not need to know who you are will not be able to see your name or contact details. Your data will be anonymized and have a code number assigned instead.

We will keep all information about you safe and secure in NHS servers.

Some of your anonymized imaging and histology data will be sent to University of Edinburgh Imaging BRICIA server on drives encrypted by the University's IT staff and only accessible by Prof. Waldman and the appropriate members of the research team. Once we have finished the study, we will keep some of the data in the University BRICIA server for 3 years 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, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital. If you do not want this to happen, tell us and we will stop.

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/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to adam.waldman@ed.ac.uk, or
- by ringing us on 0131 465 9567.

What will happen to the results of the study?

The results from this study will be written up as a part of a publication. This study is also a part of an educational qualification within the University of Edinburgh Centre for Clinical Brain Sciences. You will be provided with Edinburgh Imaging/University of Edinburgh social media channels where the research publications related to this study will be shared.

You will not be identifiable from any published results.

Following completion of your scan and your surgery 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 been removed at surgery. If you choose, your tissue and imaging data may used in other future research. The study is also registered on the ISRCTN registry for clinical trials (ISRCTN18300486), where results of the study will be published.

Who is organising and funding the research?

This study has been organised by Professor Adam Waldman and sponsored by the Academic and Clinical Central Office for Research and Development.

The study is being funded by The Edinburgh Brain Cancer Fund.

Who has reviewed the study?

The study proposal has been reviewed by through a per review process**.**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from East of England Cambridge South REC. NHS Management Approval and Edinburgh Imaging approval have also been given.

Researcher Contact Details

If you have any further questions about the study please contact Professor Adam Waldman: adam.waldman@ed.ac.uk.

Independent Researcher Contact Details

If you have any further questions about the study and would like to consult with someone independent of the study, please contact Dr. Lucy Kershaw: lucy.kershaw@ed.ac.uk.

Complaints

If you wish to make a complaint about the study please contact:

Adam Waldman,
University of Edinburgh, Chancellor's Building
49 Little France Crescent
Edinburgh EH16 4SB
adam.waldman@ed.ac.uk

OR

Gerry Thompson
University of Edinburgh, Chancellor's Building
49 Little France Crescent
Edinburgh EH16 4SB
gerard.thompson@nhslothian.scot.nhs.uk

Participant ID: **Centre ID (if applicable)**

CONSENT FORM

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Please **initial** box

1. I confirm that I have read and understand the information sheet for the above study.

*Date (DD MMM YYYY)	*Version Number

**complete during consent process*

2. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
4. I give permission for the research team to access my medical records for the purposes of this research study. ☐
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
6. I give permission for my Community Health Index (CHI) number or hospital number to be collected and retained on NHS servers for administration of the study. ☐
7. I agree to my General Practitioner being informed of my participation in the study and any incidental findings from this study. ☐
8. I understand that data collected about me during the study may be converted to anonymised data. ☐
9. I agree to my anonymised data being used for future ethically approved studies. Yes ☐ No ☐
10. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature

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