NCT04540107

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Non-Invasive Characterization of Lower Grade Glioma (LrGG) (Group 1)

This is a clinical trial, a type of research study. Your study doctor Susan Chang, MD and her team, and study investigator Tracy Luks PhD from the UCSF Department of Radiology, will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have a known lower grade brain tumor.

Why is this study being done?

The purpose of this study is to evaluate the serial changes in patients with lower grade glioma through imaging, blood sample testing, and to determine if these changes provide information on tumor progression. There are two groups for this study. Group 1 will compare conventional MR imaging sequences that will be taken as part of your clinical care with MR spectroscopic imaging taken for research purposes only. Patients of Group 2 will undergo an additional imaging exam that uses carbon-13 magnetic resonance spectroscopic imaging (^{13}C MRSI). The purpose is to determine whether patients with lower grade glioma exhibit changes in different metabolites before and after treatment. ^{13}C MRSI scan involves the injection of an investigational agent pyruvate. An investigational agent is one that has not been approved for use by the Food and Drug Administration (FDA) and is available for research only. Hyperpolarized ^{13}C Pyruvate is a non-radioactive isotope of carbon. The doses of ^{13}C Pyruvate that will be used in this study have been shown to be safe and well tolerated in a previous human study.

Who pays for this study?

This study is funded by the National Cancer Institute and University of California San Francisco, Department of Radiology and Biomedical Imaging.

How many people will take part in this study?

About 300 adults who have known lower grade glioma will take part in this study with 60 patients per year for approximately 5 years.

What will happen if I take part in this research study?
There are two groups in this study. Group 1 will have 260 patients, and group 2 will have 40 patients.

Your study doctor will tell you which group you will be participating in prior to your enrollment.

Subjects in Group 1 will receive clinical brain magnetic resonance imaging (MRI), magnetic resonance spectroscopy (MRS), and blood draw testing. Subjects in Group 2 will receive brain magnetic resonance imaging (MRI), magnetic resonance spectroscopy (MRS), blood draw testing, and ^{13}C hyperpolarized imaging.

To find out if you can take part in the study, the study doctor or a member of the research team will ask you questions about your health, current medications, medical and surgical history, and standard-of-care treatment plan. If you qualify for the study and you choose to take part, then you will have the following procedures:

Group 1:
1) Brain Magnetic Resonance Spectroscopy (MRS)

After your clinical brain magnetic resonance imaging (MRI), you will have magnetic resonance spectroscopy (MRS).
MR spectroscopy is performed at a selected region of the subject's brain that has suspected or confirmed brain tumor as well as neighboring healthy tissue. The graph that is produced as a result represents the relationship between the presence of certain chemicals that exist in brain tumors and in healthy brain tissue but in differing amounts. The information obtained using MR spectroscopy may help doctors find tumor tissue not detected by conventional MR imaging. In addition, MR spectroscopy may help doctors to better differentiate between tumor tissue, healthy brain tissue and tissue that has been destroyed by radiation or chemotherapy. MR spectroscopy may benefit tumor patients in the future but will not be used for diagnosis at this time.

You will be asked to continue to have MRS that follow the clinical MRI schedule set by your doctors to monitor your care.

2) Research Blood Test

At the time of each of your MR exams, about three tablespoons of blood sample will be drawn for research purposes only from the IV line already in place (you will not receive an extra "stick" for the research study). A separate consent for research blood collection will be given for you to review and sign. This blood sample will be processed and stored at UCSF Brain Tumor Research Center (BTRC) Tissue Bank for potential biomarker testing. A biomarker is used to measure progress of a disease or the effects of treatment. The results of these tests will not be given to you or your doctor and will not be used in planning your care. These tests are for research purposes only and you will not have to pay for them.

Your study doctors, Dr. Susan Chang and Dr. Tracy Luks, will retain your research records, including information from your medical records, for research purposes. Blood samples will also be retained for research purposes. Your medical records may be reviewed by the clinical study coordinator and research nurse coordinator to determine study eligibility, to confirm diagnosis and treatment, or to schedule appointments. The information may also be reviewed by researchers to make comparisons of other tests with the MRI exams for up to ten years after the MRI exam.

What will happen with the blood samples retrieved for research?

The blood samples collected will be used to characterize the brain tumor and how it responds to treatment. Additional tests may be done on these samples if new research techniques or tools become available. The research that may be done with your sample is not designed specifically to help you. It may help other people who have cancer and other diseases in the future. You will receive no medical benefit from allowing the use of your samples.

Study location: All imaging study procedures will be done at UCSF Parnassus, China Basin Landing or at Byers Hall at Mission Bay.

How long will I be in the study?

The length of time that you will be in the study depends on whether you agree to continue to have brain imaging exams that follow the clinical MRI schedule made by your doctor as part of your clinical treatment.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You should talk to your study doctor about any side effects you experience while taking part in the study.

- **MRS risks**
  - Additional time in the scanner may cause some discomfort or anxiety

- **Confidentiality**
  - The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private.
- **Unknown Risks**
  - Because this is research, there may be risks that are currently unforeseeable. The researchers will let you know if they learn anything that might make you change your mind about taking part in the study.

Are there benefits to taking part in the study?

There are no direct benefits for participating in this study but it is hoped that the information gained from this study will help researchers learn more about practical ways of evaluating and standardizing treatment in patients with brain tumor.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part of this study, there will be no penalty to you. You will receive the same treatment if you choose to participate on the study or not.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- National Cancer Institute (NCI).

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

What are the costs of taking part in this study?

You or your insurance will be charged for the MR exams that would be performed as regular clinical care. You will not be charged for the MRS or blood sample collection that are being performed solely for research purposes.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell Dr. Chang or Dr. Nelson, if you feel that you have been injured because of taking part in this study. Dr Chang can be reached by telephone [redacted], or you may call Dr. Luks [redacted].

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not

normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena or otherwise) about research participants.

The Certificate DOES NOT:
• stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
• stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
• stop disclosures required by the federal Food and Drug Administration (FDA).
• prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:
• from releasing information about your involvement in this research.
• from having access to your own information.

Who can answer my questions about the study?

You can talk to Dr. Chang or Dr. Luks about any questions or concerns you have about this study. Dr Chang can be reached by telephone [redacted], or you may call Dr. Luks [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please all the office of the Institutional Review Board at 415-476-1814.

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CONSENT

You have been given copies of this consent form, and the Experimental Subject's Bill of Rights. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent
Date	Witness – Only required if the participant is non-English speaker