CONSENT FOR CANCER RESEARCH

Project Title: Optimal Timing of Postoperative Magnetic Resonance Imaging (MRI) in Patients with Extradural Spinal Tumors – a Pilot Study

Principal Investigator: Lilyana Angelov, M.D.

Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at insert institution(s) Cleveland Clinic (CC) and/or University Hospitals (UH)

1. Introduction

We are asking you to participate in a research study. The purpose of this document is to summarize your discussion with the research team and provide you with written information to help you decide whether you want to participate in research. Your decision is completely voluntary.

Your treating doctor may also be an investigator on this research study. If so, your doctor will have an interest in both your welfare and in the research study. You are not required to take part in this research study offered by your doctor. You may ask for a second opinion from another doctor who is not linked to this study. If you choose not to be in this study, the quality of your regular medical care will not be affected.

Please ask any questions you may have about the study or this consent form before signing it. Please take your time to make your decision. You will be given a copy of this form to keep.

2. INFORMATION ON THE RESEARCH

You are being asked to participate in a medical research study because you are having or have just had spine tumor surgery. If you agree to participate, you will be one of 8 subjects who will be participating in this research study at the Cleveland Clinic Foundation.

This research study is evaluating suitability of a delayed magnetic resonance imaging (MRI) in management of spine tumors. Currently the standard of care is obtaining an MRI scan in the early postoperative period (within 72 hours after surgery). The purpose of this study is to see if delayed MRI (2 to 3 weeks after surgery) is similar in quality to the earlier MRI.

What is required from you in this study

In this study you will undergo 2 MRIs after the surgery instead of one MRI. You will have one MRI about 3 days after the surgery and one MRI about 2-3 weeks after surgery.

Procedure

Magnetic resonance imaging involves use of a scanner, which is a large machine that creates a magnetic field and radiowaves. It takes multiple, detailed images of the part of your body that is being studied and often guides management based on the information it provides. You will be placed inside the scanner for about 30 minutes. At some point near the end of the scan, a radiology technologist will administer intravenous contrast, which is used to better delineate any residual tumor within the tissues. A radiologist will then compare the two scans obtained with the interval of 2-3 weeks without knowing the date of the image. He or she will then go through the images in detail to decide which image gives better anatomical details and give recommendations on which time is better for imaging. The images and interpretation of the scan will be available in your electronic medical records and will be used in planning the following steps of your treatment.

3. RISKS AND DISCOMFORTS

Risks of MRI

If you take part in this research, you will have two MRI's (magnetic resonance imaging and/or magnetic resonance spectroscopy) instead of one. MRI uses a magnet and radio waves to make images (pictures) of the inside of the head and/or body. There have been no ill effects reported from exposure to the magnetism or radio waves used for these studies; however, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal that may cause injury to you. We will ask you about metal within your body (this includes certain dyes used in tattoos and body piercings). If there is any question about potentially hazardous metal within your body, you will not be able to participate in this research study. We will also keep the MRI room locked so that no one carrying metal objects enters the room while you are having this scan performed. In addition, the MRI scanner makes a loud buzzing noise that could affect hearing ability. You will be provided with earplugs and assistance in their use in order to protect your hearing. You will be able to communicate with the scanner technologist using an intercom and/or signaling device. The technologist will try to help you feel as comfortable as possible in the scanner. You can ask to stop the scan and be removed from the scanner at any time by using the intercom or signaling device.

There is a very slight risk of an allergic reaction if contrast material is injected. Such reactions usually are mild and easily controlled by medication. If you experience allergic symptoms, a radiologist or other physician will be available for immediate assistance. Gadolinium-based contrast agents (dyes) may increase the risk of a rare but serious disease called nephrogenic systemic fibrosis in people with poor kidney function. Nephrogenic systemic fibrosis triggers thickening of the skin, organs and other tissues. There is no effective treatment for this debilitating disease. In order to minimize the risks of such an event we will perform a laboratory exam (measurement of eGFR) to rule out a preexisting kidney disease.

4. BENEFITS

There may or may not be any direct benefit to you. Potentially better image quality may improve results of stereotactic radiosurgery (SRS). If SRS is indicated in your case, the second MRI may allow more accurate planning of this procedure. If SRS is not an option for you, there is no personal benefit to you from this study.. The information obtained from this study may support change to the current clinical practice if the delayed MRI scan is of good quality. The delayed scan may be more comfortable than the early post operative MRI.

5. ALTERNATIVES

The alternative is not to participate in this study. Your decision not to participate will not impact your current of future care at Cleveland Clinic.

6. PRIVACY AND CONFIDENTIALITY

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Dr. Lilyana Angelov and the research staff at Cleveland Clinic for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

Include the Name or class of persons involved in the research such as research collaborators, sponsors, and others who will have access to data that includes PHI. Choose all that are applicable and insert:

- The Food and Drug Administration;
- The Department of Health and Human Services;
- The National Cancer Institute (NCI);
- Other Institutional Review Boards;
- Data Safety and Monitoring Boards;
- Insert other parties as appropriate

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to Dr. Lilyana Angelov, Cleveland Clinic, 9500 Euclid Avenue S73, Cleveland, Ohio 44195, (216) 444-4253. Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic and/or University Hospitals will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) and/or University Hospitals Institutional Review Board assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

7. RESEARCH-RELATED INJURIES

If you experience physical injury or illness as a result of participating in this research study, medical care is available at the Cleveland Clinic elsewhere; however, the Cleveland Clinic has no plans to provide free care or compensation for lost wages.Further information about research-related injuries is available from the Institutional Review Board (IRB) at (216) 444-2924.

8. VOLUNTARY PARTICIPATION

Your participation in this research study is completely voluntary. You have the right not to participate and the right to withdraw at any time during the course of the study without fear of penalty or loss of medical care. You will be informed of any new findings that may affect your willingness to participate.

9. QUESTIONS ABOUT RESEARCH

If you have any questions regarding the research or develop a research-related problem, you should contact Dr. Angelov's office at the Cleveland Clinic at (216) 444-4253. During non-business hours you should contact the spine fellow on call at the Cleveland Clinic Foundation by calling (216) 444-2200 and requesting the operator to page this fellow. If you have questions about your rights as a research project subject, you should contact the IRB at (216) 444-2924.

10. COST and COMPENSATION

The study will pay for one of the two MRI's that is done for this research study. Procedures or drugs that are considered standard of care will be the responsibility of you or your insurance company. This includes your surgery, one post-operative MRI, and all other treatments related to your condition. You are responsible for all co-pays and deductibles.

You will not be paid for your participation in this study.

11. SIGNATURE

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date