

Radiologic Pathologic Correlation of Advanced MR Imaging to Guide the Biopsy of Cerebral Malignancies

NCT03458676

Status	RECRUITING
Phase	Not Applicable
Sponsor	M.D. Anderson Cancer Center
Enrollment	62 participants

Plain Language Summary

This study is evaluating whether advanced MRI techniques (including blood flow, water movement, and chemical analysis imaging) can accurately guide surgeons to the most dangerous areas within a brain tumor, improving biopsy precision.

****You may be eligible if...****

- You are over 18 years old
- You have a brain lesion that is suspected to be or has already been confirmed as a primary brain tumor
- You are scheduled for brain tumor surgery or biopsy
- You are able to undergo MRI with contrast dye
- You can understand and provide consent to participate

****You may NOT be eligible if...****

- Your anatomy makes a safe brain biopsy impossible
- You have severe kidney disease (which makes contrast dye unsafe)
- You have a pacemaker, metal implants in your head, or other devices incompatible with MRI
- Your doctors determine that the brain scan cannot be safely performed

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (4)

- Patient is >18 years old, agrees to participate in the clinical study and to complete all required visits and evaluations. The pediatric population has a different disease profile from the glioma patients we hope to recruit. To reduce heterogeneity in the patient population we will not consider patients younger than 18 for this study.
- Patient is a candidate for cerebral tumor resection with lesion suspected to be or previously biopsy proven to be a primary brain tumor.
- Patient is able to understand and give consent to participation in the study.
- Patient agrees to undergo, prior to the procedure, magnetic resonance imaging (MRI, within 14 days and preferably with 3 days of the planned procedure) with perfusion, diffusion and spectroscopic imaging. As per study chair's judgement, imaging outside this time window will also be permitted, for suspected slow growing tumors.

Exclusion (15)

- The patient is found to have unfavorable anatomy to indicate that stereotactic biopsy could not be safely performed.
- Renal failure as evidenced by a GFR of less than 30 mL/min/1.73m² for gadolinium based imaging, for iodinated contrast agent we will use the more strict cut-off of 45 mL/min/1.73m² (Davenport, 2020, Radiology: Use of IV Iodinated contrast media in patients with Kidney Disease: Consensus statement from the ACR and the National Kidney Foundation). This differentiation reflects the different risk profiles of these agents, and are conservative when compared to our clinical practice. In the absence of eGFR lab result, patient is not excluded in the absence of remarkable pathological renal history as confirmed by and in the

<https://clinicaltrials.gov/study/NCT03458676>

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discretion of the PI. As per current departmental guidelines, late-generation gadolinium contrast agents (such as gadobutrol and gadopiclesol), can still be administered safely in the setting of low renal function, provided clinical risk-benefit is maintained.

- Pacemakers, electronic stimulation, metallic foreign bodies and devices and/or other conditions that are not MR safe, which include but are not limited to:
 - electronically, magnetically, and mechanically activated implants
 - ferromagnetic or electronically operated active devices like automatic cardioverter defibrillators and cardiac pacemakers
- ... and 10 more (see full listing online)

Locations (1 total)

University of Texas MD Anderson Cancer Center, Houston, Texas, United States