

*Trial Innovation Network Expression of Interest:
SUpratotal vs Gross-total Resection for Glioblastoma: The SUGR Trial*

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| Study Title | SUpratotal vs Gross-total Resection for Glioblastoma: The SUGR Trial | |
| Funding I/C | PCORI | |
| Study Description | <p>Hypothesis: SpTR for non-eloquent primary GBM confers OS benefit compared to GTR without a negative impact on neurologic outcomes, ability to pursue adjuvant treatments, or quality of life. Based on historical trials in GBM treatment, 10% percent improvement in OS will be defined as the "benchmark" for success; while the trial is powered to detect a significant treatment difference, survival curves will be presented illustrating OS differences at all study timepoints.⁹ 1. Demonstrate significantly improved OS for patients undergoing SpTR vs. GTR for primary GBM based on a prospectively, simple randomized clinical trial 2. Determine PFS/recurrence; initiation/completion of adjuvant therapy; rates of early/long-term complications; and differences in patient-reported QOL metrics for primary GBM patients undergoing SpTR vs. GTR 3. Quantify the impact of primary GBM molecular markers and residual FLAIR volume following surgical resection upon survival, recurrence, morbidity, neurologic function, overall performance status, and patient-reported QOL in patients undergoing SpTR vs GTR for primary GBM.</p> | |
| Study Design | To test this Hypothesis, we have designed a randomized clinical trial conforming to the Comparative Effectiveness Research model. Eligible patients will be randomized to undergo SpTR or GTR in equal proportions. Patients enrolled during the Feasibility phase will continue scheduled follow-up and will be included in the analysis for the Full-Scale Study Phase. | |
| IRB | Johns Hopkins School of Medicine IRB | |
| Coordinating Center | Johns Hopkins (CCC) and University of Utah (DCC) | |
| Study Length | Participant duration: 24 months | |
| Study Enrollment # | 400 | |
| Eligibility Criteria | <p><u>Inclusion Criteria</u></p> <ul style="list-style-type: none"> • Age ≥ 18 years • Karnofsky performance status KPS <70 • Individuals with a suspected, contrast-enhancing primary HGG on MRI brain imaging who are brought to neurosurgery clinic or the inpatient neurosurgery service as part of their routine care will be identified for study inclusion by their neurosurgeon (or delegate). • Patients must be subsequently proceed with resection as part of standard of primary GGG care and have histologically confirmed primary HGG in order to remain in the study. • Confirmed primary HGG must be centered in the right frontal lobe, right anterior temporal lobe, left anterior temporal lobe, right occipital lobe, or left occipital lobe based upon routine brain MRI with and without contrast • Participant surgeon will consist of board-eligible or board-certified neurosurgeons with brain tumor sub-specialty, published work on HGG patient outcomes, and at least 50 craniotomies for brain tumor resection performed per year. | <p><u>Exclusion Criteria</u></p> |
| Total # of Sites | 30 | |
| Site Requirements | <p><u>Study sites will need to have the following at their site to be considered:</u></p> <ul style="list-style-type: none"> • Performs at least 40 HGG resections per year • At least 30% of surgical patients return to the site for chemo radiation • Research staff with experience in randomized trials | |
| Site Investigator Qualifications | <p><u>Site Investigators should have the following:</u></p> <ul style="list-style-type: none"> • Board-certified neurosurgeon • Performs at least 10 HGG resections per year • Willing to randomize participants to SpTR vs. GTR | |

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| Key Timeline Dates: | <p><u>The following dates are projections and subject to change:</u></p> <p>Site Selection Decisions: March 2026 Site Selection Notifications: March 2026 Enrollment begins: December 2026 Last Patient/Last Visit: March 2031 Study Closure: March 2032</p> |
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