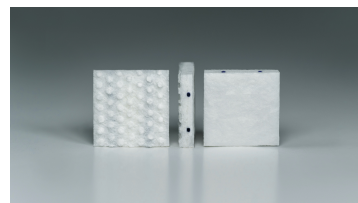


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BACKGROUND:

Resection (R) followed by single or multi-fraction stereotactic radiotherapy (SRT) lowers surgical bed recurrence free survival (SB-RFS) for brain metastases compared to R alone. Nevertheless for larger brain metastasis (≥2.5 cm) 12-month recurrence rates after R+SRT can exceed 20-30%. Aiming to improve these outcomes, a permanently implanted collagen tile brachytherapy (CTBT) device (GammaTile, GT Medical Technologies, Tempe AZ) utilizing Cs-131 was developed to safely deliver immediate adjuvant radiotherapy (RT) and achieve RT dose intensification. The device received FDA clearance for this indication, based on a single-arm study due to the excellent safety and efficacy as measured by SB-RFS. It is hypothesized that R+CTBT will increase the time to post-resection-recurrence, while prolonging survival and reducing the impact on functional and neurocognitive status compared to R+SRT.



STUDY DESIGN:

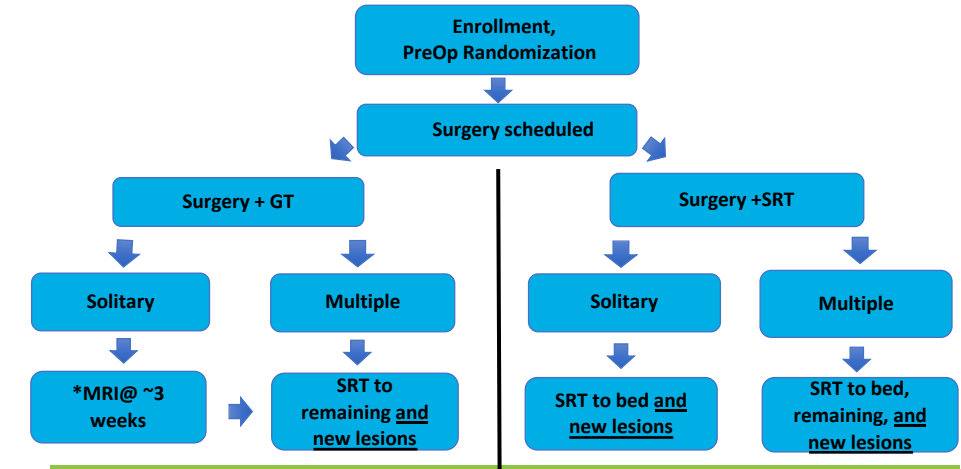
- Multicenter (up to 5 institutions), prospective, randomized, parallel group, controlled Phase 3 trial
- N=180 subjects with resectable, previously untreated “index” brain metastases lesions measuring ≥2.5-5 cm and 0-3 other tumors will be preoperatively randomized 1:1 to undergo either R+SRT or R+CTBT to the index lesion; unresected tumors in both groups will receive single-fraction or multi-fraction SRT
- Follow-up will be at 1,3,6,9,12,16 and 24 months
- Initiation of enrollment targeted for Q3 2020

OUTCOMES:

- Primary Endpoint:**
- Surgical bed-recurrence free survival (SB-RFS)
- Secondary Endpoints:**
- Overall survival
 - Quality of life (Functional Assessment of Cancer Therapy-Brain, Linear Analog Self-Assessment)
 - Neurocognitive Function (Hopkins Verbal Learning Test-Revised, Trail Making Tests, Controlled Oral Word Association)
 - Functional status (Karnofsky Performance Scale, Barthel-ADL)
 - Treatment related adverse events

Key Inclusion Criteria	Key Exclusion Criteria
<ul style="list-style-type: none"> • Aged 18 years and above • Newly diagnosed brain metastases (“index” lesion) ≥2.5 cm appropriate for surgical resection • Up to 3 non-index lesions < 4.0 cm are allowed • KPS score of ≥70 	<ul style="list-style-type: none"> • Past SRT to the index lesion • Prior radiation to index or other lesions to be treated on-trial • Prior whole brain radiation • Primary germ cell tumor, small cell carcinoma, or lymphoma • Leptomeningeal metastasis

STUDY FLOW:



CONCLUSIONS:

This will be the first randomized trial comparing R+SRT versus R+CTBT(GammaTile). Primary and secondary outcome measures will be captured to elucidate the potential risks and benefits of these two differing approaches for patients with newly diagnosed metastatic brain tumors.

*GT Medical Technologies is the trial sponsor.