BRIDGES

A Clinical Trial for Newly Diagnosed GBM

Patient Considerations

Exploring Participation in the BRIDGES Randomized Clinical Trial

For Patients with Newly Diagnosed Glioblastoma Needing Resection

WHAT IS THE BRIDGES RANDOMIZED CLINICAL TRIAL?

The BRIDGES Clinical Trial (GTM-105) is a randomized clinical trial for people who have been newly diagnosed with a glioblastoma (GBM) brain tumor and need surgery. The purpose of this study is to find out if adding GammaTile® during surgical removal of a brain tumor improves survival outcomes compared to standard of care treatment.

Standard of Care (SOC): Tumor removal surgery followed by 6 weeks of external beam radiation therapy (EBRT) and oral chemotherapy (temozolomide, TMZ), followed by additional cycles of TMZ. EBRT delivers radiation therapy from outside of the body and usually begins about 4 weeks after surgery.

GammaTile: GammaTile is an FDA-cleared, implantable radiation therapy device placed directly in the surgical cavity at the time of tumor removal surgery. Each GammaTile is made of a 2 cm × 2 cm collagen square/tile that contains four radioactive sources (about the size of a grain of rice). Once implanted, GammaTile begins delivering radiation immediately, right where the tumor was removed. The tile does not need to be removed – the collagen is safely absorbed by the body over time, while the radiation sources remain safely in place.

Both GammaTile and EBRT are FDA-cleared for the treatment of malignant (cancerous) brain tumors and available to patients.

Randomization: Everyone who joins the study is placed into a treatment group at random, which means by chance, like flipping a coin or drawing a name from a hat. For every three participants, two will be assigned to the GammaTile group and one to the SOC group. This means you have about a two-in-three chance of receiving GammaTile in addition to standard therapy, and a one-in-three chance of receiving standard therapy alone. Neither you nor your doctor can choose your group.

- **Group A:** Surgery will be performed to remove as much of the tumor as safely possible. After surgery, patients will receive 6 weeks of radiation therapy from outside of the body (EBRT) together with chemotherapy (TMZ), followed by additional cycles of chemotherapy (TMZ).
- **Group B:** Surgery will be performed to remove as much of the tumor as safely possible, with GammaTiles placed in the tumor site at the end of surgery. After surgery, patients will receive 4 weeks of radiation therapy from outside of the body (EBRT) – a shorter course since part of the radiation dose is delivered by GammaTile – together with chemotherapy (TMZ), followed by additional cycles of chemotherapy (TMZ).

WHAT IS AN RCT?

A randomized controlled trial (RCT) is a type of clinical study used to find out if a new treatment or medical approach works. In an RCT, participants are randomly (by chance) assigned to one of two or more groups. One group receives the new treatment, and the other group receives the standard treatment. In this way, the RCT tests if a new treatment or a standard treatment is more effective.

WHY IS THIS STUDY IMPORTANT?

Glioblastoma (GBM) is one of the most aggressive brain tumors. The standard of care is a well-established treatment pathway but requires a delay in radiation for surgical healing. The BRIDGES trial aims to determine if adding GammaTile can extend survival and improve patient outcomes. By participating, you play a critical role in shaping the future of care for patients with GBM.

WHY SHOULD I JOIN THIS CLINICAL TRIAL?

Participating in the BRIDGES Clinical Trial offers several potential benefits:

Access to Advanced Treatment: This trial offers a unique opportunity to receive immediate radiation with GammaTile in addition to the standard therapy. Both approaches are designed to target the tumor site effectively.

Contribute to Groundbreaking Medical Research: By participating in the BRIDGES Trial, you're helping doctors study the most effective way to treat GBM. Your participation could make a difference in developing better treatment options for future patients with GBM.

High-Quality & Expert Care: Whether you receive GammaTile and external radiation therapy or external radiation therapy, you will receive targeted radiation therapy from leading experts in treating GBM. The BRIDGES Trial follows strict guidelines to ensure your safety, ensuring you receive excellent care throughout your entire treatment protocol.

Close Monitoring of Your Health: The BRIDGES Trial includes frequent health assessments, so your condition will be closely watched.

WHAT CAN I EXPECT DURING THIS CLINICAL TRIAL?

If you decide to participate in the BRIDGES Clinical Trial, the process generally includes:

1. **Informed Consent:** Before joining, your doctor will discuss the study's purpose, procedures, and potential risks in detail so you can make an informed decision about whether to participate and sign a form acknowledging your consent to join.
2. **Screening and Enrollment:** After consenting, you'll undergo a screening process to confirm you meet the trial's eligibility criteria. This may involve medical tests and assessments to verify that the trial is suitable for you.
3. **Randomization and Treatment Protocol:** You will be assigned to a treatment group at random, which means by chance. It's like flipping a coin, but not a 50/50 split. For every three people who join the study, two will be placed in the treatment group and one will be placed in the comparison group. This means you have about a two-in-three chance of receiving the treatment being studied and a one-in-three chance of receiving the current standard treatment.
4. **Strict Health Monitoring:** Throughout the trial, you'll be closely monitored by a healthcare team to assess how the treatment is working. You'll have regular checkups and may undergo additional medical imaging and tests to evaluate your response to the treatment.

ARE THERE ANY RISKS INVOLVED?

As with any medical treatment, both treatment pathways involve potential risks, like side effects or the chance that the treatment may not work as expected. The research team will inform you of any known risks before you join. Your health and safety are the top priority; the clinical trial includes safety protocols to protect you throughout the process.

HOW TO DECIDE IF THIS CLINICAL TRIAL IS RIGHT FOR ME?

Talk with your treatment team about how the BRIDGES Trial fits with your diagnosis and treatment goals. Review the eligibility requirements, weigh the potential benefits and risks, and discuss your options with your doctor and loved ones. For more information, reach out to the study coordinators or your healthcare team. Making an informed decision is essential to your treatment journey.

WHAT QUESTIONS SHOULD I ASK MY DOCTOR BEFORE JOINING?

- Why am I a good candidate for this trial?
- What treatments or interventions are being tested/will I receive?
- What are the chances I'll receive GammaTile and external radiation therapy or external radiation therapy only?
- Will I know if I am receiving GammaTile?
- How does this trial compare to the standard treatment for my condition?
- What are the potential risks and benefits?
- What can I expect during the trial, and how long will it last?
- How might this trial impact my daily life?
- Can I continue taking my regular medications during the trial?
- What happens if my condition worsens during the trial?
- Will I be able to leave the trial if I change my mind?
- How will my privacy and personal health information be protected?

HOW CAN I JOIN THIS CLINICAL TRIAL?

If you're considering participating in this clinical trial, please talk with your doctor or email our study coordinators at clinicalaffairs@gtmedtech.com.

GammaTile®

GammaTile® is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms. The potential for, and symptoms of, adverse events related to radiation exposure vary depending on the radiosensitivity of the exposed tissue, the amount of radiation delivered, and the placement of GammaTile(s). GammaTile should not be used for patients with a known history of hypersensitivity to bovine-derived materials. More information on indications, contraindications, warnings, and instructions for use can be found in the GammaTile Instructions for Use.

CAUTION: The law restricts these devices to sale by or on the order of a physician.