

SUMMARY FOR PATIENTS AND FAMILIES

PBTC-061: Phase 2 Trial of G207 + 5 Gy Radiation for Children with High-Grade Gliomas,” ([NCT 04482933](#))

This study is being undertaken by the Pediatric Brain Tumor Consortium (PBTC). The PBTC is a group dedicated to improving treatment options for childhood brain tumors. It is made up of fifteen academic centers and children's hospitals in the United States and Canada.

The following is a summary of a clinical trial, a therapeutic research study. Clinical trials include only patients who choose or whose parents permit them to participate in the research study. Participation is entirely voluntary.

Who might be eligible to participate in PBTC-061?

- Patients with a confirmed diagnosis of high-grade glioma whose disease has worsened or returned for the first time are eligible to participate in this study.
- Patients must be 3 years or older at the time of initial diagnosis and less than 22 years old to join this study.
- Patients must have received surgery and radiotherapy as part of their previous treatment.
- Patients will undergo clinical evaluations to confirm eligibility prior to starting the trial.

Why is PBTC-61 being undertaken?

There is no effective standard treatment for high-grade glioma. This research will examine a drug called G207 in combination with a single dose of radiation to see if this approach is better or worse than the usual treatment for high-grade glioma.

G207 is an experimental herpes simplex virus (HSV). HSV causes cold sores and, rarely, causes a severe brain infection. G207 has been genetically changed and weakened, in the hope that only cancer cells will be infected and killed by the virus, without harming normal brain tissue.

What is involved in this study?

If you decide to take part in this study, a magnetic resonance image (MRI) of your head will be done. If the MRI shows that you are eligible for this study, a surgery day will be set. On that day, you will be taken to the operating room and will receive anesthesia. This surgery involves opening your skin over the skull and cutting a hole in the skull to access the tumor.

If your tumor is smaller, a procedure called a biopsy will be done to confirm if the cancer is growing. If your tumor is larger, a procedure called debulking will be done. Debulking is the surgical removal of as much of the tumor as possible and is more invasive than a biopsy. If debulking is done, you will have another MRI after your surgery. If this post-operative MRI shows that the cancer is still too big, the doctor will talk to you about an additional surgery to remove the tumor before continuing treatment on this study.

If the specimens taken via biopsy or debulking show that your tumor is growing back, the doctor will surgically place catheters into the remaining tumor. Following this surgery, you will undergo a computed tomography (CT) scan to confirm the location of catheters in your tumor. If needed, the doctor will adjust the position of the catheter tip by withdrawing it to a more desirable location. The catheter(s) will be hooked to a syringe pump, and G207 will be pumped in during a 6–8-hour infusion. During the infusion, you will be able to move around your room as tolerated with assistance from your nurse. After the infusion, the catheters will be removed, and you will be watched for any side effects. The day after you receive the G207 infusion, you will receive a single dose of radiation. If there are no complications after you recover, you will remain in a regular hospital room for an estimated 2-3 days to be watched for any side effects.

After leaving the hospital, you must call the clinic immediately if there are any concerns. After the treatment, you will be required to return to the clinic for evaluation at 7, 14, and 28 days; 3, 5, 7, 9, 12, 15, 18, 21, and 24 months; and yearly thereafter for up to 5 years from the start of protocol therapy.

What are the risks of participating in PBTC-61?

If you choose to take part in this study, there is a risk that treatment with G207 and a single dose of radiation may not be as good as the usual approach for your cancer.

There is also a risk of side effects from the G207 and radiation. These side effects may be worse and may be different than you would get with other treatments for your cancer.

Some of the most common side effects that the study doctors know about are:

- Headache
- Loss of appetite
- Nausea
- Vomiting
- Tiredness
- Fever
- Muscle weakness

There may be some risks that the study doctors do not yet know about.

QUESTIONS ABOUT THIS STUDY?

If you would like more information, please contact the PBTC member institution closest to you. You can also contact the doctor in charge of this study:

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OTHER INFORMATION IS AVAILABLE THROUGH

The National Cancer Institute's Cancer Information Service at 1-800-422-6237 or TTY: 1-800-332-8615 or through the National Cancer Institute's websites www.cancer.gov and www.cancer.gov/clinicaltrials.