

PBTC-021 - A SUMMARY FOR PATIENTS AND FAMILIES

Title: A Phase I Trial of Radiation Therapy and Concomitant Capecitabine Rapidly Disintegrating Tablets in Children with Newly Diagnosed Brainstem Gliomas and High Grade Gliomas

This is a brief summary of a clinical trial, a type of therapeutic research study. Clinical trials include only patients who choose, or whose parents permit them, to take part in the research study. Participation is entirely voluntary.

WHO MIGHT BE ELIGIBLE TO PARTICIPATE IN PBTC-021?

Children between 3 and 21 years of age may be eligible. Eligible patients will have a newly diagnosed high grade malignant glioma. They may have had surgery recently for their tumor but may not have received any chemotherapy. Eligible patients may have a brain stem glioma, anaplastic astrocytoma, glioblastoma multiforme or other high grade glioma that has not spread in the brain. Patients with anaplastic oligodendroglioma are not eligible to participate in PBTC-021. Patients who are pregnant or breast-feeding cannot participate in this clinical trial.

Patients will need medical tests to assess whether they can participate in PBTC-021. These tests may include a medical history, physical examination, blood and urine tests and scans (MRI) of the brain and spine. Other tests may be required if doctors believe they are necessary. About 25 children from throughout the U.S. will take part in PBTC-021.

WHY IS THIS STUDY BEING DONE?

Current treatment for highly malignant gliomas in children is radiation therapy, and survival rates are poor. PBTC-021 tests a new investigational drug in combination with radiation therapy. This new drug is called capecitabine.

Capecitabine is an anti-cancer drug that is approved by the Food and Drug Administration for adults with certain types of colon cancer. In laboratory studies with brain tumors, researchers have found that radiation therapy increases the amount of an enzyme (chemical) that may make capecitabine more active against a brain tumor.

In PBTC-021, participants will receive radiation therapy along with capecitabine in the form of “Rapidly Disintegrating Tablets.” Radiation therapy has been studied in combination with capecitabine in a small number of adult patients with different kinds of tumors. PBTC-021 is the first time this combination is being evaluated in children with brain tumors. The purposes of this study are to:

- Find the highest dose of capecitabine that can be given in combination with radiation therapy without causing severe side effects
- See what side effects (good or bad) may occur when radiation therapy and capecitabine are given together
- Learn how a child’s body processes capecitabine by studying fluids of the body.

- Find out how well radiation therapy and capecitabine work together in the treatment of brain tumors in children.

Doctors and researchers are conducting PBTC-021 in the hopes of finding a more effective treatment for highly malignant gliomas in children.

WHAT IS INVOLVED IN PBTC-021?

Participants will receive capecitabine twice a day in pill form. They will begin to take capecitabine on the same day that they start radiation therapy. They will continue to take capecitabine tablets 2 times a day every day while they receive radiation therapy. Radiation therapy lasts about 6 weeks and is usually not given on weekends. However, participants will continue to take capecitabine tablets twice a day on the weekends and on any other days when radiation is not given.

Capecitabine needs to be swallowed whole with water within thirty minutes after eating a meal. If a participant can't swallow pills, capecitabine tablets can be dissolved in water that is room temperature and then swallowed.

Once radiation therapy is completed, participants will continue to take capecitabine tablets 2 times a day every day for 3 more weeks. This means that participants will take capecitabine tablets for a total of 9 weeks in a row.

For the next 2 weeks, participants will not take any capecitabine tablets. A schedule of 2 weeks on pills and one week off will continue until the study schedule is completed, about 20 weeks total.

To see how capecitabine and radiation therapy together affect the brain tumor, participants will need scans of the brain (MRI, MRS, PET-FDG, MR perfusion/diffusion, ECHO gradient MRI), some of which can also provide information on the chemical activity within the brain. Doctors may require a spine scan if they believe it is necessary. To monitor participants' condition both during and after their participation in PBTC-021, doctors will conduct physical examinations, blood tests and other routine medical tests necessary for patient care.

Doctors will request permission from parents and patients to study very small amounts of blood for laboratory research during the 20 weeks that participants will be on PBTC-021. These tests can determine how much of the drug stays in the blood (pharmacokinetic study) and will help understand how capecitabine works.

WHAT ARE THE RISKS OF PARTICIPATING IN PBTC-021?

Doctors monitor patients carefully for any side effects or other problems. They may give patients other medicines to lessen the side effects

The most commonly reported side effects of capecitabine include diarrhea, nausea, vomiting, mouth sores, abdominal pain, constipation, and difficulty digesting food. Other reported side effects may be related to capecitabine when it is given with radiation therapy. These side effects may include low blood counts, fatigue, skin and other problems.

There may be unknown risks and discomforts involved in participating in this or any clinical trial. Doctors will notify parents and patients immediately of any important information or treatment findings discovered during the study that may affect their willingness to continue to participate.

QUESTIONS ABOUT PBTC-021?

If you would like more information, please contact the [PBTC member institution](#) closest to you. You can also contact the doctors 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:

- cancer.gov
- [CancerTrials](#): comprehensive clinical trial information
- [CancerNet](#): accurate cancer information