

PBTC-030 - A SUMMARY FOR PATIENTS AND FAMILIES

Title: A Phase II Trial of Capecitabine Rapidly Disintegrating Tablets and Concomitant Radiation Therapy in Children with Newly Diagnosed Brainstem 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-30?

Children may be eligible who are between 3 years and 17 years of age and who have a newly diagnosed, non-disseminated intrinsic infiltrating brainstem glioma. Eligible patients must have received no prior treatment for their brain tumor other than dexamethasone and/or surgery. Patients' medical and neurological condition must be stable at the time they begin to participate in the trial.

Patients will need medical tests to assess whether they can participate in PBTC-030. These tests may include a medical history, physical examination, blood and urine tests, and scans of the brain and spine (MRI). Other tests may be required if doctors believe they are necessary. About 34 children throughout the United States will take part in PBTC-030.

WHY IS PBTC-030 BEING DONE?

Current standard treatment for highly malignant gliomas in children is radiation therapy. Survival rates are poor with this treatment. PBTC-030 tests a new drug called Capecitabine in combination with radiation therapy in the hope that this combination will be a more effective treatment for children with brainstem glioma than radiation therapy alone.

The drug used in this study, Capecitabine, comes in the form of rapidly disintegrating tablets. It is an anti-cancer drug, which is approved for use in adults for certain types of cancers. Laboratory studies show that standard radiation therapy increases the effect of Capecitabine on the tumor by increasing enzyme levels in the tumor.

Specifically, PBTC-030 will –

- Determine how well the combination of Capecitabine and radiation therapy work together to treat children with brainstem gliomas
- Determine how the body processes Capecitabine by studying fluids of the body

- To learn more about what side effects (good or bad) may occur when radiation therapy and Capecitabine are given together.

WHAT IS INVOLVED IN THIS STUDY?

There are 2 phases of treatment in PBTC-030. During the first phase (called the “Radiation Phase”), children will take Capecitabine tablets 2 times a day every day that they have radiation therapy. This combination treatment will continue for 6 weeks. Children will continue to take Capecitabine tablets twice a day for 3 more weeks after radiation therapy is completed. Then there is a 2-week break when children do not take any pills. This phase of treatment takes 11 weeks.

The second treatment phase (called the “Post Radiation” phase) is 9 weeks long. In this phase, children will take an increased dose of Capecitabine tablets. They will take pills twice a day for 2 weeks then skip a week. This on-off schedule will continue for the total 9-week phase.

The doctors will give you a diary with the dosing schedule to help you keep accurate records.

Your child will have a routine physical exam and a blood test every week and a neurological exam every few weeks. Scans of the brain are required 2 times during the treatment period, once midway and once upon completion.

PBTC-030 lasts about 20 weeks. Your child will receive follow up MRIs every three months for three years once the treatment phases are over.

WHAT ARE THE RISKS OF PARTICIPATING IN PBTC-030?

Doctors watch study participants very carefully for any side effects or other problems. However, doctors do not know all the side effects which may occur. Side effects may be mild or very serious. Other medicines may be given to lessen side effects. In some cases, side effects may be long lasting or may never go away. There is also a risk of death. Many side effects may go away soon after a child stops taking the Capecitabine.

Some of the frequent side effects of Capecitabine are diarrhea, nausea, vomiting, mouth sores, abdominal pain, constipation and difficulty digesting food. When Capecitabine was given with radiation to adults, they experienced swelling, redness and peeling of the skin on the hands and feet, low blood count, nausea and decreased appetite.

QUESTIONS ABOUT PBTC-030?

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:

Lindsay Kilburn, MD
Department of Hematology/Oncology
Texas Children's Cancer Center
6621 Fannin, CC 1410.00
Houston, TX 77030
Telephone: (832) 824-4615
Email: lbkilbur@txccc.org

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. There is additional accurate and reliable information at www.cancernet.org