



GLIOX Trial (CTPR-0017): Patient Information

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Why is this clinical trial being done?

The GLIOX trial aims to compare intraoperative radiation therapy (IORT), with external beam radiation therapy (EBRT) for the treatment of recurrent glioblastoma (GBM). IORT is a localized form of radiation therapy allowing Radiation Oncologists and Neurosurgeons to work together to deliver a full course of radiation therapy in just one treatment. This dose of radiation is delivered at the time of surgery while you remain under anesthesia. In comparison, EBRT typically requires 20-30 radiation treatments over a period of six or more weeks.

This trial will examine whether IORT is as effective as EBRT, both utilizing the drug Bevacizumab as part of the treatment plan. Bevacizumab is a man-made antibody used to treat certain types of cancer, including recurrent GBM. All patients enrolled in this study will be treated with the Xoft IORT system at the time of surgery. The results will be compared to another study of patients treated with EBRT.

demonstrated promising clinical results researching the Xoft System for brain cancer. The GLIOX Trial aims to replicate the results yielded from the EMC study, which may further measure the practicality and benefit of IORT for your specific condition.

Details about the Gliox Trial

How many people will participate in this clinical trial

Up to 100 patients will be enrolled in the clinical trial.

How long will I be in this clinical trial?

The radiation delivered intraoperatively will be completed at the time of your surgical procedure. Patient monitoring and treatment with Bevacizumab will continue up to three years.

Before you begin this clinical trial

There are several exams, tests and procedures to see if you are eligible to participate in the clinical trial. Some of these exams



The Xoft IORT System

Xoft® Axxent® Electronic Brachytherapy (eBx®) System® is FDA cleared, CE Marked and licensed in a growing number of countries for the treatment of cancer anywhere in the body including the brain. The Xoft IORT System uses the world's smallest x-ray source to precisely deliver a concentrated, single dose of radiation directly to the tumor site, while minimizing risk of damage to healthy tissue.

Over the last 10 years, the Xoft IORT System has been used on more than 15,000 patients with early-stage breast cancers, nonmelanoma skin cancers, and gynecological tumors. The European Medical Center (EMC) in Moscow, one of the largest private medical clinics in Russia, for the last four years have

are part of a routine cancer care monitoring regardless if you are enrolled in the clinical trial.

Exams include:

- History and physical exam, including a complete neurological evaluation
- A questionnaire about your general well-being
- Pregnancy test (if you are a woman of child-bearing potential)
- Magnetic Resonance Imaging (MRI), which utilizes magnetic fields and radio waves to generate images rather than x-ray or ionizing radiation. In order to enhance the MRI images a contrast agent (dye) will be injected into your vein
- Blood and urine tests



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What to expect on the day of surgery?

During the procedure your neurosurgeon and a team of trained specialists will place a flexible balloon applicator in the area where the tumor has been removed. A proprietary miniature x-ray source is inserted into the balloon applicator to deliver the full course of radiation treatment. The IORT part of your surgical procedure takes around 20 minutes. Once the radiation treatment is complete, the miniature radiation device will be turned off. The balloon applicator is then removed and the neurosurgeon will close the incision.

Participation in this clinical trial includes:

- IORT (Intra Operative Radiation Therapy) at the time of tumor removal
- MRI images, acquired 24-48 hours after surgery
- Administration of Bevacizumab every two weeks, starting 28 to 56 days after surgery

- Follow up visits (including MRI imaging) are scheduled at four and eight weeks after surgery. Then visits will move to a cycle of every eight weeks for the remainder of three years.

The follow up schedule in this study is very similar to what is recommended as routine care for patient with Glioblastoma.

If your tumor progresses, follow-up visits will be scheduled every 12 weeks for the remainder of the three years.



FAQ

What is clinical research?

The term “clinical research” describes studies to collect new information on human health and disease. Volunteering to take part in clinical research helps the medical community find better ways to prevent, diagnose, or treat disease.

Am I required to be in this clinical trial?

No. Participation in this clinical trial is voluntary. If you choose to participate in this study, you may leave at any time. The development of new medical treatments would be impossible without the help of research participants. By volunteering in a study, you will help others by contributing to medical research. You could also help researchers to learn about a disease or condition. In some cases, you can try a new drug, procedure, or device before it is available outside of research studies; however, they may not work better than the ones that are already available.

Are there benefits to taking part in the clinical trial?

Benefits of participating include the potential avoidance of up to 20-30 additional visits for standard external beam radiation therapy, as well as immediate delivery of radiation focused on the tissue most susceptible to tumor recurrence. Combining IORT with Bevacizumab can increase the chance that those parts of the tumor not affected by radiation will be sufficiently treated as well.

What side effects or risks can I expect from being in the clinical trial?

Sometimes there may be side effects that surgeons and research may not yet know about when conducting new treatment procedures. We encourage you to speak with the research team about the potential risks and side effects.

Is it safe for my family to be with me after IORT treatment?

Yes, the radiation source is turned off and completely removed at the time of surgery.

Where can I get more information about participating in this clinical trial?

A description of this clinical trial is available on <http://www.ClinicalTrials.gov>, which provides information about federally and privately supported clinical trials. For more information about Xoft Brain IORT, visit <https://www.xoftinc.com/brain-iort.html>.

**The Xoft System is FDA-cleared,
CE marked commercially available worldwide.**



GLIOX Trial is registered on: www.clinicaltrials.gov
Study Identifier: NCT04681677

Notes:



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