The "GLIOX" Trial

The inflatable balloon provides a minimally invasive approach, fast procedure implementation, and an easy workflow

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

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A Phase II Study of Patients with Recurrent **Gli**oblastoma Treated with Maximal Safe Neurosurgical Resection, **Intra-O**perative Radiation Therapy (IORT) Using the **Xoft**® Axxent® Electronic Brachytherapy System and post-radiation adjuvant Bevacizumab (GLIOX)

Main Principal Investigator

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Inclusion Criteria-Summary

1. Histopathologically proven diagnosis of GBM or variants with unequivocal radiographic evidence for tumor progression / recurrence.
2. Interval of 6 months or greater between completion of prior radiotherapy and enrollment.
3. Recurrent GBM must be potentially-resectable with the intent to resect such that residual tumor rim is less than 1 cm enhancing disease.
4. Recurrent GBM must have the appropriate dimensions to allow a Xoft applicator balloon to fit into the tumor cavity.
5. Prior history of standard dose CNS radiation of 60 Gy in 30 fractions or 59.4 Gy in 1.8 Gy fractions, or equivalent or lower doses.
6. Minimum of 7 days must have elapsed after CNS related core or needle biopsies prior to registration.
7. Must be ≥ 18 years of age and a Karnofsky Performance Score ≥ 60%
8. CBC/differential obtained within 14 days prior to enrollment, with adequate bone marrow function.
9. Liver and renal function test should reflect adequate hepatic and renal function 14 days prior to enrollment.
10. Urine analysis should reflect no significant proteinuria within 14 days before enrollment.
11. Patients on full-dose anticoagulants must meet additional criteria including in range INR.
12. Women of child-bearing potential must have a negative pregnancy test at baseline screening.
13. Subjects of child-bearing potential must agree to use adequate contraceptive precautions and not to breastfeed until six months after the end of the treatment with Bevacizumab.

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Exclusion Criteria Summary

1. More than three relapses.
2. Tumors in or near critical brain structures (optic system) that would exclude sufficient dose to tumor margin.
3. Evidence of multicentric, infratentorial, or leptomeningeal recurrent disease.
4. Recurrent or persistent tumor greater than 6 cm in maximum diameter.
5. Prior therapy with any inhibitor of VEGF(R).
6. Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 1 year.
7. Women who are pregnant or nursing.
8. Women with child-bearing potential or sexually active men that are not willing / able to use medically acceptable forms of contraception.
9. Contraindications for MRI with or without gadolinium.
10. Contraindications for anesthesia / surgery.
11. Enrolled on another therapeutic clinical trial concurrently.
12. Suffers severe, active co-morbidity (specifications in protocol).
13. Prior history of hypertensive crisis or hypertensive encephalopathy.
14. History of a non-healing wound, ulcer, or bone fracture within 90 days prior to enrollment.
15. Gastrointestinal bleeding or any other hemorrhage / bleeding event > CTCAE v.5 grade 3 within 30 days prior to enrolment.
16. Hypersensitivity to Bevacizumab.

Study Profile

Design and Objective	Single-arm, prospective, multi-center, historical controlled, non-randomized, non-inferiority study of subjects treated with single fraction, intra-operative radiation therapy at the time of surgical resection of recurrent GBM followed by Bevacizumab 28-42 days after surgery. Results will be compared to a historical control arm, the EBRT and Bevacizumab arm of RTOG-Trial 1205.
Endpoints:	
Primary	Overall Survival
Secondary	• Progression-free Survival (PFS) • 4 weeks progression • Local + Distant PFS • 6 Months PFS rate • Quality of Life • Neurotoxicity • Adverse Events
Exploratory	Centralized Image Review
Scope	100 Subjects: Up to 25 centers worldwide
Duration	3 year follow-up
IORT Dose	20 Gy
Bevacizumab Dose	10mg/kg every 2 weeks, starting 4-6 weeks post surgery

FAQ

Is the Xoft Axxent eBx System cleared by FDA?

Yes, the Xoft Axxent eBx System and balloon applicator have been cleared by the U.S. FDA. In addition, both maintain CE Mark for Europe.

What will it cost to participate in the trial?

Your Xoft Representative will discuss the different options.

Will Xoft provide support with IRB/EC submissions?

Yes, upon request, Xoft Clinical Affairs will provide your center with assistance in preparing your study-related IRB/EC submissions.

What kind of data entry system will be used?

The data will be captured using a web-based data capturing system.

For more information, contact Clinical Affairs: clinicalaffairs@xoft.com
We are also registered on clinicaltrials.gov: www.clinicaltrials.gov
Study Identifier: NCT04681677

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