

A Global, Multicenter, Prospective, Controlled, Open-Label Pivotal Study of Iodofalan (131I) Solution for Injection (TLX101-Tx) Plus Lomustine Versus Lomustine Alone in Patients With Radiographically Confirmed Recurrent Glioblastoma at First Recurrence (IPAX BrIGHT [IPAX-3])

Clinical summary

This global clinical trial will evaluate how safe and effective the investigational treatment called TLX101-Tx in combination with lomustine chemotherapy compared to lomustine alone in people with first recurrence of glioblastoma.

TLX101-Tx delivers targeted radiation to glioblastoma cells. The trial is conducted in two parts: Part 1 assesses safety and radiation dosing; Part 2 is a randomised comparison of the combination therapy against standard of care treatment.

In Part 1, cohorts of participants will receive different doses of TLX101-Tx and lomustine. If the drug is not well tolerated, the dose will change in new groups of participants and additional arms of the study will open. Doctors watch closely for any serious side effects, which helps them decide when the dose is too high.

Conditions

This trial is treating patients with first recurrence or progressive glioblastoma after first-line treatment

Trial Acronym

IPAX BrIGHT

Cancer

Glioblastoma (GBM)

Trial Identifiers

NCT07100730
131I-TLX-101-003
2025-521785-10

Age: 18+

Phase: III

For full trial details, visit trials.cancervic.org.au/details/vctI_nct07100730