Evaluation of ex Vivo Drug Combination Optimization Platform in Recurrent High Grade Astrocytic Glioma

NCT05532397

Status	RECRUITING
Phase	Not Applicable
Sponsor	National University Hospital, Singapore
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (10)

- Pre-screening:
- Patients 21 years of age or older, with ECOG performance status 0 to 2, and with a life expectancy of more than 3 months with suspected high grade astrocytic glioma, fit for treatment comprising standard-of-care therapy with adjuvant temozolomide and radiotherapy if the diagnosis of high grade astrocytoma is pathologically confirmed.
- Signed informed consent obtained before any study specific procedure. Subjects must be able to understand and be willing to sign the written informed consent.
- Patients will be enrolled at the time of initial surgery but study imaging and further PDO generation will not take place if the patient is subsequently found not to meet the histological criteria or will not be receiving standard adjuvant temozolomide/ radiotherapy.
- All subsequent criteria apply to the main study only:

... and 5 more (see full listing online)

Exclusion (5)

- Chemotherapy, radiotherapy, surgery, immunotherapy or other therapy within 2 weeks of study entry.
- Pregnancy or breastfeeding at the point where systemic anti-cancer therapy is initiated. Women of childbearing potential must have a negative pregnancy test at the point where systemic anti-cancer therapy is initiated. Women of childbearing potential and men, must agree to use adequate contraception (barrier method of birth control) while on anti-cancer treatment and until at least 3 months after the last study drug administration.
- Concurrent cancer which is distinct in primary site or histology from the cancer being evaluated in this study EXCEPT cervical carcinoma in situ, treated basal cell carcinoma, superficial bladder tumours (Ta, Tis \& T1) or any cancer curatively treated less than 5 years prior to study entry.
- Patients with leptomeningeal dissemination of disease and/or pure spinal high grade gliomas will be excluded.
- Kidney disease which would clinically disqualify the subject from serial MRI scans with gadolinium contrast.

Locations (2 total)

Department of Hematology-Oncology, National University Hospital, Singapore, Singapore
Ng Teng Fong General Hospital, Singapore, Singapore