

**CNS Site Clinical trials/Studies
January 2007**

Open to accrual

1) IND.170 (Lapatinib) – Dr Brian Thiessen, PI

***N.B. Interim analysis being conducted – on hold**

An oral EGFR tyrosine kinase inhibitor

Study Objectives

Phase I study:

In patients receiving EIAED's, a phase 1 dose-finding study will be performed to identify a maximal tolerated dose for further phase 2 study. Pharmacokinetic studies will be done in this patient population to identify how GW572016 is metabolized in patients taking EIAED's.

Phase II study:

- 1) To assess the efficacy, as determined by objective tumor response rates, of GW572016 when administered daily in appropriate recommended doses to patients with recurrent GBM.
- 2) To evaluate immunohistochemical measures of cellular proteins and receptors in paraffin embedded tumor samples for potential correlates of GW572016 anti-tumor activity
- 3) To determine the pharmacokinetics of GW572016 in patients enrolled in the phase 2 portion of the study.

Patient Selection Criteria

- 1) patients with histologically confirmed glioblastoma multiforme in first relapse following radiation therapy either alone or in combination with adjuvant chemotherapy.
- 2) Bidimensionally measurable enhancing disease on CT or MRI
- 3) ECOG performance status 0,1 or 2
- 4) age \geq 18 years.
- 5) Prior therapies:
 - Surgery: $>$ 2 weeks from any major surgery
 - Chemotherapy: no more than one prior chemotherapy regimen in the adjuvant setting.
 - 6 weeks since last dose of chemotherapy. No chemotherapy for recurrence.
 - Radiation: At least 6 weeks from end of radiation.
- 6) Acceptable hematologic parameters and LVEF $>$ 50%
- 7) Accessible for treatment and follow-up
- 8) Signed consent form

Study nurse: Susan D'Aloisio - pager 03078 local 2364

2) CE.5 - NCIC (Primary Chemotherapy with Temozolomide vs Radiotherapy in Patients with Low-grade Gliomas After Stratification for Genetic 1P/19Q Loss: A Phase III Study) – Dr Brian Thiessen, PI

Study Objectives

To demonstrate a difference in PFS for primary treatment with temozolomide in order to assess:

- 1) whether PFS and OS can be prolonged by primary chemotherapy with temozolomide
- 2) whether the incidence of late toxicity can be decreased by using primary chemotherapy
- 3) the toxicity profile of the two treatments
- 4) the QOL of patients

Patient Selection Criteria

At Registration:

- 1) Histologically proven low grade (WHO grade II) diffuse glioma: astrocytoma (gemistocytic, fibrillary, protoplasmatic), oligoastrocytoma, oligodendroglioma, supratentorial location only
- 2) ECOG \leq 2
- 3) \geq 18 years

At Randomization:

- 1) Requiring treatment as demonstrated by one of the following:
 - Age \geq 40 years
 - Radiologically proven progressive lesion
 - Neurological symptoms other than seizures alone (focal deficits, increased intracranial pressure, mental deficits)
 - Intractable seizures
- 2) Not a candidate for treatment by surgery exclusively
- 3) RTOG neurological function 0-3
- 4) Results of genetic (1p) testing available
- 5) Adequate hematological, renal and hepatic parameters
- 6) No previous RT or chemotherapy, and sufficient recovery from surgery
- 7) No secondary cancers, with the exception of adequately treated basal cell skin carcinoma

Treatment Arms

- 1) Radiotherapy 50.4 Gy/28 x 1.8 fractions
- 2) Temozolomide 75 mg/m² daily x 21 days every 28 days until progression or for a maximum of 12 cycles

Study Nurse: Kikine Capier - Local 2370 pager 03733

3) Measurement of Functional Impairments and Adaptational Efforts in Persons with Malignant Gliomas: A Prospective Mixed Methods Study – Maureen Parkinson, PI

Open at VCC and FVCC

Study Objectives

To document in a prospective fashion the specific disabilities faced by brain tumour patients, and describe the compensatory strategies and efforts made to adapt to these impairments. Specifically, we intend to answer the following:

1. What are the functional impairments and disabilities related to fulfilling activities of daily living, as reported by persons with high-grade gliomas and their family caregivers, over time from pretreatment through post-treatment?
2. What are the specific coping and compensatory strategies developed by patients and caregivers to help them adapt to these challenges, and how effective have these been?

Patient selection criteria

- 1) \leq age 70
- 2) \geq KPS 70
- 3) prior to beginning planned chemoradiation
- 4) newly diagnosed with a malignant glioma grade 3 or 4
- 5) ability to speak English.
- 6) primary caregiver also willing to participate

Study contacts: Maureen Parkinson, Rosemary Cashman, Michael McKenzie
(Research assistant to be assigned)

4) Complementary Therapy Decision Making Processes of Advanced Cancer Patients – Dr. Lynda Balneaves & Tracy Truant, co-PIs**Study Objectives**

To understand the CAM decision making process and information needs of advanced cancer patients (i.e. non-curative intent). Data from this qualitative study will inform the development of CAM decision making and information support resources within the conventional cancer care system.

Patient selection criteria

- 1) Able to speak English
- 2) \geq 18 years

- 3) Have been told by their oncologist that the intent of their cancer treatment is non-curative
- 4) Using or considering using any form of CAM for their cancer

Study contact: Bindy Kang 604 822 5199

Pending

- 1) TRANSMID – Xenova - (Convection enhanced surgical delivery of diphtheria toxin conjugated with transferrin vs Standard care for non-resectable, progressive or recurrent GBM: a Phase III study) – Dr B Toyota
- 2) NCIC mTOR inhibitor study
- 3) RESCUE – Schering/CBTC-sponsored (dose-dense temozolomide 28 day regimen for recurrent malignant glioma) - Dr B Thiessen
- 4) “The elderly study” - Schering (modified Stupp protocol 40Gy + temozolomide) – Dr B Thiessen