Diagnostic and Prognostic Markers in Low-Grade Glioma

**Purpose of Study:**
1) To evaluate diagnostic and prognostic relevance of alterations of specific chromosomes & chromosomal regions using PCR analysis of microsatellite repeats and FISH.
2) To evaluate diagnostic and prognostic relevance of DNA ploidy by flow cytometric analysis and compare this with ploidy determinations by FISH.
3) To assess diagnostic & prognostic relevance of various markers of cellular proliferation and cellular function.

**Study Chairs:**
Jan C. Buckner M.D.  
Robert M. Arusell M.D.

**QC Specialist:**
Helen J Tollefson

**Statistician:**
Wenting Wu Ph.D.

**Nurse Resource:**

**Status:**
12/01/1995  Activated

**Projected Number of Patients:**
99999

**Excluded:**
2

**Final Accrual:**
NA

**Stratification:**
None

**Schema:**
PCR, FISH, flow cytometry, & immunohistochemical determinations performed in the laboratory of Dr. R. B. Jenkins & the Mayo Cancer Center Pathology Laboratory

**Study Design:**
Original Design: This prognostic factors study was designed to evaluate a battery of tumor markers in patients with low-grade astrocytomas, oligodendrogliomas, or mixed oligoastrocytomas who were enrolled in 2 clinical trials for newly-diagnosed low-grade gliomas, i.e., the first NCCTG-led intergroup phase-III trial in this population (86-72-51) and a then-ongoing Mayo/NCCTG phase-II trial (93-72-02). The dataset will consist of the prospectively-collected clinical data from these 2 trials together with associated baseline tumor marker data measured on paraffin-embedded tissue collected from each of the clinical trials participants at the time s/he enrolled in the trial.

While the blocks were being collected from the NCCTG member institutions, several new potential markers that could be measured in paraffin-fixed tissue were identified by participants in the NCI-sponsored Glioma Markers Network (GMN) to which Mayo belongs.

Revised Design: In order to enhance the likelihood of finding the most prognostic markers associated with this disease, the NCCTG Translational Research Committee and the GMN participants jointly agreed to include in the univariate and multivariate analyses to be done in this protocol those promising GMN markers that were approved by both of them. Appendices justifying the new markers were added to the original protocol, and the revised protocol was approved by the NCCTG IRBs during 1998.
Accrual: This study was activated by NCCTG on 12/1/95. By the cutoff date for this report (3/24/09), blocks from 135 patients from 12 memberships had been registered for this study, as shown in the Accrual Table. These comprise blocks from 134 (49%) of the 275 patients enrolled in the 2 low-grade glioma trials (100/232 in 86-72-51, 34/43 in 93-72-02) plus one erroneously registered block from a GBM patient enrolled in 98-72-52.

Currently, there are 128 eligible registrations and 7 registrations that have been disqualified for various reasons. One patient cancelled out of 93-72-02 between registration and submission of pathology materials, and 6 blocks were declared ineligible for this study. In addition to the GBM block improperly registered into this study instead of the corresponding high-grade glioma study (94-72-52), the blocks for 4 patients enrolled in low-grade glioma trials were declared ineligible upon routine neuropathology review. Two were reclassified as high-grade glioma (1 AA, 1 AOA); one was classified as a ganglioma; and one could not be definitively classified as astrocytoma, oligodendroglioma, or oligoastrocytoma. A sixth block was typed as astrocytoma but was not graded by the neuropathologist due to concern about the representativeness of the biopsy sample.

Patient Characteristics: The 135 patients with blocks registered for this study consist of 54 women (40%) and 81 men. One is classified as an ethnic minority. The histologic classifications for the 128 eligible blocks are summarized in the Histologic Classification Table included in the Spring 2006 report.

Available Information: Virtually complete and up-to-date clinical and follow-up data are available for all patients who participated in either of the 2 NCCTG clinical trials in newly-diagnosed low-grade glioma. Deaths have now been recorded for 83 (61%) of the patients registered to this study.

Study Status: Acquisition of tissue blocks from patients enrolled in the recently-closed low-grade clinical trial continues. Eighty-three deaths are documented in this prognostic factors study -- 47% of the 171 so far recorded in the 2 low-grade glioma trials (155 in 86-72-51, 16 in 93-72-02).

The following reports have been presented.

Manuscripts:


Abstracts:


**Accrual Table:**

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<th>Total Entered</th>
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<td>Total Membership Accrual</td>
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