

WEB AD – PIOGLITAZONE AND ISOTRETINOIN

Each year in the United States approximately 17,000 people are diagnosed with primary malignant brain tumors CBTRUS (2000). Malignant glial tumors, including anaplastic astrocytoma and GBM, exact a tremendous toll on patients because of the severe neurological disability they produce. Despite optimum treatment modalities of maximal tumor removal, radiation, and adjuvant chemotherapy, the prognosis for these tumors is bleak with survival rates of 12 to 18 months (Neurosurgery, 1991).

Peroxisome Proliferator-Activated Receptor Gamma (PPAR γ) – a hormone receptor – has been found to be elevated in high grade, malignant glioma (cancer) cells.

Pioglitazone, an FDA-approved, oral antidiabetic medication has demonstrated it is a potent and highly selective inhibitor of PPAR γ . By its effects on PPAR γ , Pioglitazone causes tumor cell death and blocks the tumor cells from duplicating.

Isotretinoin, an FDA-approved oral medication and a potential anti-neoplastic (abnormally growing tissues) also prevents the development of preneoplastic lesions and may inhibit the growth of established cancers. It has, in its composition, retinoic acid (a form of Vitamin A) and has been shown to help slow or disrupt the growth of human breast cancer cells and has properties that induce cell death.

If you agree to take part in this study, there may or may not be direct medical benefit to you. The possible benefits of taking part in the study are the suppression of these proteins that have shown to be elevated in malignant brain tumors. However, no benefit is guaranteed.

The purpose of this Phase I Study is to determine the safety, effectiveness and toxicity of Pioglitazone and Isotretinoin in patients with recurrent or progressive malignant gliomas.

Patients may be considered for this protocol if they fulfill the following criteria:

- Age \geq 18 years

- Recurrent or progressive malignant glioma
- Karnofsky performance status > 40%
- Baseline laboratory data within an acceptable range
- Patients with diabetes or on oral hypoglycemic agents are excluded

Study duration and time commitment required of study subjects

The study duration is 1 year. Patients will receive active treatment for six months. If patients are observed to have progressive disease, they will be removed from the study. If a response of stable disease, partial or complete response is observed, patients will be eligible to continue therapy. Patients will be followed for up to 1 year. Study procedures include blood tests (every 2 weeks for the first month and then monthly) and questionnaires (each monthly visit).

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