

Phase I Study To Test The Safety of TVAX Immunotherapy As A Treatment For Recurrent Grade III/IV Gliomas

This study is currently recruiting participants.

Purpose: TVAX Immunotherapy is an experimental treatment that takes advantage of the fact that your body can produce immune cells, called 'killer' white blood cells that have the ability to kill large numbers of the cancer cells that are present in your body. TVAX immunotherapy is designed to generate large numbers of those 'killer' white blood cells and to deliver those cells into your body so that they can kill your cancer cells.

Primary Outcome Measures: To determine the relative toxicity (safety) of vaccinating recurrent grade III/IV glioma patients four times with live, attenuated cancer cells combined with granulocyte-macrophage colony-stimulating factor (GM-CSF). Toxicity will be assessed following delivery of each treatment component.

Secondary Outcome Measures: The potency of the modified vaccination regimen will be assessed by measuring immune responses following each vaccination. The study is designed to determine whether vaccinating recurrent grade III/IV glioma subjects four times with attenuated cancer cells stimulates more powerful immune responses than vaccinating subjects twice. Clinical effects also will be measured to determine whether the treatment causes the cancer to regress.

Detailed Description: The TVAX Immunotherapy involves several steps. First, the patient's cancer will be surgically removed to provide cells for the vaccine. Second, the patient will be vaccinated twice with those cells and GM-CSF. Third, the patient's blood will be filtered for white cells which will then be cultured and stimulated to reach a higher (killer) activity level. Fourth, the activated T cells will be infused into the patient's bloodstream so that they will be able to attack the cancer. Fifth, the patient will receive a course of low-dose interleukin-2 (IL-2), which stimulates the T cells to continue to multiply after they are in the body. Finally, the entire process starting with vaccination and ending with IL-2 injections will be repeated, for a total of two rounds of therapy.

Inclusion Criteria:

- Age > 18
- Informed consent
- Diagnosis of grade III or IV glioma with progression following standard treatment.
- Must be able to tolerate surgery to provide tumor tissue for vaccine.
- Must be able to produce viable vaccine from tumor tissue.
- Eastern Cooperative Oncology Group (ECOG) performance status must be ≤ 2
- Negative HIV test.
- Negative for hepatitis B and C virus.
- Respiratory reserve must be reasonable.
- Sufficient renal function.
- Satisfactory blood counts
- Negative pregnancy test for women of childbearing potential.

Exclusion Criteria:

- Surgically removed cancer reveals that it is not grade III/IV glioma.
- Concomitant life-threatening disease.
- Active autoimmune disease is exclusionary.
- Currently receiving chemotherapy or biological therapy for treatment of cancer.
- Currently receiving immunosuppressive drugs for any reason.
- Corticosteroids beyond peri-operative period.
- Psychological, familial, sociological or geographical conditions that do not permit adequate medical follow-up and compliance with the study protocol.

Contacts and Locations:

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