MEMORIAL SLOAN-KETTERING CANCER CENTER
CURRENT CLINICAL TRIALS

A Phase I Study of Intrathecal Radioimmunotherapy Using ^{131}I-8H9 for Central Nervous System/Leptomeningeal Cancers

[Protocol 03-133]

Full Title :

PHASE I STUDY OF INTRATHECAL RADIO IMMUNOTHERAPY USING 131I-8H9 FOR CENTRAL NERVOUS SYSTEM/LEPTOMENINGEAL NEOPLASMS

Purpose :

The purpose of this study is to find the highest safe dose of a new medicine, a radioactive antibody called ^{131}I-8H9, in children and adults with cancer of the brain or brain covering (leptomeninges) that has returned after standard treatment or for which no standard therapy exists.

Antibodies are made by the body to fight infections, and in some cases, to fight tumors. The antibody 8H9 is made by mice and can attack many kinds of tumors. The medicine being evaluated in this study consists of 8H9 attached to radioactive iodine (^{131}I). This drug has been given by vein to patients to see if it can find cancer cells. This is the first study assessing ^{131}I-8H9 given into the spinal fluid ("intrathecally") to kill cancer cells.

A Phase II Study of Intrathecal I^{131}-3F8 in Patients with GD2-Expressing Central Nervous System and Leptomeningeal Neoplasms

[Protocol 05-122]

Full Title :

PHASE II STUDY OF INTRATHECAL 131I-3F8 IN PATIENTS WITH GD2-EXPRESSING CENTRAL NERVOUS SYSTEM AND LEPTOMENINGEAL NEOPLASMS

Purpose :

Malignant tumors in the brain and/or spinal cord are life-threatening. Radiation therapy is often helpful in controlling tumor growth. This study is evaluating a new medication that delivers focused radiation to tumor cells. The purpose of

this research study is to investigate whether multiple injections of this drug will be safe and effective in controlling malignant tumors of the brain and/or spinal cord.

The drug, an antibody called 3F8, is a protein that attaches to tumor cells. When radioactive iodine is attached to the antibody, it is referred to as I^{131}-3F8. When I^{131}-3F8 attaches to a tumor, it delivers radiation directly to the tumor. The I^{131}-3F8 is put into an Ommaya reservoir, a permanent small plastic tube placed in one of the ventricles of the patient's brain by a neurosurgeon.

Before the I^{131}-3F8 injection, patients will receive a variety of other medications to protect the thyroid gland from the radioactivity and to prevent allergic reactions and fever.

MEMORIAL SLOAN-KETTERING CANCER CENTER
PEDIATRIC CLINICAL TRIALS
PLANS FOR THE FUTURE

Humanized Antibodies For Tumors That Arise In Or Spread To The Brain

Cancers that arise in the brain or spread to the brain are devastating. In recent years, brain metastasis is becoming more urgent as systemic cancer is getting under better control. Once a cancer appears in the brain, time is more pressing and the outlook doubly dismal unless these agents can be expeditiously applied. For cancers like neuroblastoma, in the past there were no survivors when the tumors spread to the brain. In the last five years the outlook has dramatically changed. At Memorial Sloan-Kettering Cancer Center (MSKCC), we are convinced that monoclonal antibodies when used appropriately can give these children a second chance. Besides neuroblastoma, patients with primary brain tumors (e.g. medulloblastoma and astrocytoma) and those with metastatic cancers to the brain (e.g. breast cancer, lung cancer or melanoma) may also benefit from these treatments.

Despite these preliminary successes, we have obstacles that need to be overcome. These prototype drugs are made from mouse white cells and are sometimes quickly rejected by the human body. MSKCC researchers have developed methods to change the genetic blueprint of these antibodies so that they look like human. These humanized antibody treatments can now be repeated so that all remaining tumor cells are eliminated. Another obstacle inherent in all orphan diseases (like pediatric cancer) is that orphan drugs are not money making; even when they are effective, there is no incentive for large drug companies to develop and produce them. To move ahead with this research, we appeal to foundations and individuals to help support drug development and manufacturing so that children can benefit from new and more effective treatments.

We have a mouse antibody 8H9 with great promise for tumors that arise from or spread to the brain. Humanizing this antibody will assure its acceptance by the human body and further enhance its effectiveness. In the first stage of research we build the cell "machine" that will make the humanized antibody. In the second stage, we will run the machine to make the drug. The first stage will cost around $250,000 and should take less than six months to complete. In the meantime we will raise funds for the second stage. The new drug should be ready for trials within two years. Your commitment from Kallan's Klan will help to support important projects such as this with the goal of developing better treatments for young patients with brain cancers.