

2.0 NON-TECHNICAL ABSTRACT

Squamous cell cancer of the head and neck is a cancer that can involve the mouth, throat or voice box and spread to lymph glands in the neck. It usually occurs in older men with a history of tobacco and alcohol use. In the year 2000, approximately 40,300 new cases will be diagnosed, and 11,700 people will die from the cancer in the United States. Patients usually present with advanced disease. Despite treatment with surgery, chemotherapy drugs, radiation therapy (treatment with X-rays), or a combination of these, only 30-50% of patients will be cured. Recurrence is very common, and no treatment has been shown to extend the lives of people with recurrent disease.

A gene called E1A may be able to stop the growth of cancer by making the tumor cells die or making them more sensitive to other cancer treatments like radiation therapy. The E1A gene is obtained from a small part of the DNA of a common col virus. It can be introduced into tumor cells by combining it with a bit of lipid or fat, then giving it by injection directly into tumors. In this case, the combination is called E1A-Lipid Complex (1:1). E1A-Lipid Complex (1:1) has been given to mice in experimental models of head and neck cancer. It has been shown to be safe, to make the tumors smaller, and to help the mice with cancer live longer.

E1A-Lipid Complex (1:1) has also been used in small numbers of people. It has been injected directly into the tumors of 33 patients with head and neck cancer, and nine patients with breast cancer. None of the patients who received the E1A Lipid Complex (1:1) had any serious side effects. The sizes of the tumors were measured by CT scan before and after treatment. Overall, the tumors of five patients became smaller, and the tumors of 16 patients stayed the same size. Special tests done on biopsy specimens from some of the patients after treatment showed that the gene was successfully transferred to the cells and was making proteins.

Although E1A-Lipid Complex (1:1) has been shown to be safe, it only decreased the size of the tumors a modest amount. Tests in the laboratory have shown that the E1A gene can make other cancer treatments, like radiation therapy, work better. To help determine whether or not E1A-Lipid Complex injections combined with radiation therapy make tumors smaller, up to 50 patients with squamous cell head and neck cancer that has worsened despite previous treatment with radiation therapy will be enrolled into a study.

For the study, patients will receive radiation therapy, which is usually given five days a week for six to seven weeks, and twice-weekly injections of E1A-Lipid Complex (1:1) into the tumors during the course of radiation therapy. The tumor response will be measured by comparing CT scans both before and after the study treatment. Patients will be watched closely for side effects during and after treatment. The rates of these side effects will be compared to the rates of side effects from radiation therapy alone, which are well-described from previous studies in the medical literature.