

Non-technical abstract

Title: Phase II Trial of Surgery with Perioperative RPR/INGN 201 (Ad5CMV-p53) Gene Therapy Followed by Chemoradiotherapy for Advanced, Resectable Squamous Cell Carcinoma of the Oral Cavity and Oropharynx (S0011).

The purpose of this study is to evaluate the feasibility of using RPR/INGN 201 during surgery and the effect it has on head and neck cancer. Once a tumor is removed by surgery, RPR/INGN 201 will be injected into the surrounding tissue. This research is being done because we want to see how well RPR/INGN 201 works when given during surgery for head and neck cancer.

The gene transfer agent we are studying, RPR/INGN 201, uses an altered adenovirus as the carrier to deliver the normal p53 gene to cells. Preliminary laboratory studies have suggested that a gene, called p53 (a tumor suppressor gene), can slow or stop the growth of tumors. In order to get a copy of the p53 gene into cancer cells, a virus called an adenovirus will be used. The adenovirus, in its naturally occurring form, is a type of virus commonly associated with respiratory problems, such as the common cold. The adenovirus has been changed in the laboratory so it cannot grow in the body, but can penetrate cells and transfer the human p53 gene.

In phase II studies approximately 25% of patients with recurrent head and neck cancer achieved tumor growth control when treated with RPR/INGN 201. In order to try to slow tumor recurrence or stop the cancer, a mixture of RPR/INGN 201 (p53 gene and a cold virus) will be injected directly into the tissue that surrounded the tumor using a needle. This procedure will be done peri-operatively while patients are still asleep.