ABSTRACT FOR GENERAL PUBLIC

Lung cancer is the leading cause of cancer death for men and women in the United States. This clinical trial proposes to test the safety of a gene therapy for advanced lung cancer. We will use a common cold virus that has been altered so that it can not duplicate in tissue. This virus will have a suicide gene inserted into it. Patients with advanced lung cancer will have this virus injected into their lung tumor through a long needle inserted through the skin. In addition, the patient may have a procedure where a flexible tube is passed down the lung airways and a small needle the size of the end of a pencil passed through the tube to inject the tumor if it is visible. A second bronchoscopy with the tube will be done 2 days later to perform a small biopsy of the tumor obtaining tissue about the size of the end of a pencil to see if the suicide gene is in the tumor tissue. A drug called Cytovene® is given daily by vein for 7 days. The suicide gene in the lung cancer cells changes Cytovene® into a drug that can kill the tumor cell. In addition, neighboring tumor cells may be killed by the drug and this is called the bystander effect. We will escalate the dose of the virus to three levels with at least three patients in each level. We will obtain blood tests, to test safety of the virus, and to determine if there is an immune response against the virus. Chest x-rays will be done before and after to see if there is any change in tumor size. If this treatment is shown to be safe, future studies will determine how effective this treatment might be.