

SECTION: 3 CLINICAL PROTOCOL

3.1 NON-TECHNICAL ABSTRACT

The incidence of melanoma, a type of skin cancer, has been increasing faster than any other cancer with 56,000 cases diagnosed per year in the United States. It accounts for 1-2% per year of all cancer deaths in the U.S. Estimates project that 1 in 75 persons will develop melanoma in their lifetime. Unfortunately, there is nothing currently available for the complete treatment of this type of cancer.

This protocol is an investigation of a new drug, which is a combination of lipids (or fats) and DNA (genetic material) and is injected directly into the bloodstream. This drug works by delivering DNA to sites of tumor cell growth. The drug being used in this study, Pro-1 works in conjunction with an anti-viral drug, Valtrex[®] (valacyclovir hydrochloride), which is already approved by the U.S. Food and Drug Administration. Pro-1 and Valtrex work together to cause apoptosis (natural cell death) in cancerous cells that are actively dividing. Since normal cells don't divide as frequently as cancerous cells, we expect this treatment will have a minimal impact on normal cells. This process of delivering genetic material to cancer cells is referred to as gene transfer.

The process of gene transfer involves introducing small portions of genetic material into cells of the body. This genetic material is derived from pieces of DNA from the human herpes virus and is grown in bacteria. In this protocol, the study drug is composed of the pieces of DNA contained within a tiny sphere composed of lipids. These spheres, with the DNA in them, travel through the bloodstream and find their way to the tumor where they work in conjunction with Valtrex to induce apoptosis.

The purpose of this research is to see whether Pro-1 in combination with Valtrex can be safely given to patients with metastatic melanoma. There have been no previous human studies of Pro-1; however, laboratory research in animals suggests that Pro-1 can act against melanoma. In this study we want to learn what dose of the drug is safe for humans and see how long Pro-1 stays in the blood.