

Non-Technical Abstract

This trial will examine injection of a virus carrying the gene for an immune system stimulating substance called IL-12 into superficial tumor nodules in patients with surgically incurable melanoma. Injection of the virus into a melanoma tumor nodule will cause tumor cells to make IL-12 at relatively high local concentrations. It is thought that this substance can alter the environment within the tumor nodule to facilitate development of a more effective antitumor immune response. This immune response could activate immune system cells called T cells which circulate in the bloodstream and could potentially attack melanoma tumor cells located at distant sites from the injected nodule. We have chosen injection into a tumor nodule because the virus can produce a local environment favorable for the development of an immune response with minimal toxicity. This initial study will emphasize safety, confirmation of the ability of the virus to produce IL-12 within a tumor nodule, evaluation of the immune system cells and molecules found within an injected nodule and antitumor effects within injected and uninjected nodules. The outcome of the study should be a dose and injection schedule of the viral vaccine which is safe and provides a characterized local effect in a melanoma tumor nodule for subsequent trials which have as their primary end points evaluation of immune responses and antitumor effects elicited by this investigational vaccine.