Lay Language Summary

Liver cancer is one of the leading causes of cancer death in the world. Excluding the very small percentage of patients that can be cured with aggressive surgery or liver transplantation, the great majority of patients with liver cancer have no effective treatment and will die of their disease.

In this clinical trial we intend to stimulate the immune system to attack the liver cancer cells. We have described that alpha fetoprotein (AFP), a protein that in adult life is only expressed in patients with liver (50-80% of them) and testicular cancers, can be used to generate immune responses to liver cancer cells. When mice were immunized with AFP they were protected from liver cancers that made AFP. Similarly, when cells from healthy human donors were stimulated with AFP they killed human liver cancer cells in the laboratory. We have immunized liver cancer patients with pieces of AFP protein, both in an oil-and-water emulsion as well as on potent immune-stimulating cells called dendritic cells. In both of these early clinical trials, the majority of liver cancer patients activated their immune system against the AFP protein and the vaccines were safe.

In this trial we will administer 3 doses of DNA that codes for AFP then one booster injection of a defective cold virus that also makes AFP, to liver cancer patients. This is a potentially powerful way to make the immune system respond to fight cancer cells making AFP. Patients will be enrolled into 3 treatment groups, in a conventional early "dose-escalation" clinical trial design, where all patients receive the same amount of DNA, but 3 different doses of the cold virus. We will monitor the safety and toxicity of this treatment, as well as the stimulation of the immune system and the clinical outcome.