B) Non-Technical Abstract

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. Dendritic cells, a special kind of blood cells, are ideally equipped to stimulate the immune system. We have recently shown that alpha fetoprotein (AFP), a protein that in adult life is only expressed in patients with liver and testicular tumors, can be used to generate immune responses to liver cancer cells. Mice immunized with dendritic cells modified to express the AFP gene were protected from liver cancers. Similarly, when cells from healthy human donors were stimulated with dendritic cells expressing the AFP gene, they killed human liver cancer cells in the laboratory.

In this trial, we will generate dendritic cells from patients with liver cancers, modify them genetically to express the AFP gene, and administer them back to the patients as three intradermal vaccinations administered once every two weeks. Subjects will be accrued sequentially to six treatment groups in a conventional phase I dose-escalation clinical trial design. We will monitor the safety and toxicity of this treatment, as well as the stimulation of the immune system and the clinical outcome.