2. Non-technical Abstract

There are virtually no effective therapeutic options for patients with metastatic renal cell carcinoma (RCC). It is possible, however, that the body's own immune system could be stimulated through a tumor vaccine to respond to RCC cells in much the same way that vaccines against common infectious diseases stimulate the immune system to protect against those illnesses. It is apparent that tumor cells have surface proteins, known as 'antigens', that are unique to the tumor, and which should in principal stimulate an immune system response. Tumor cells lack, however, certain surface protein molecules which are also essential to initiating an immunologic response. One such protein, known as B7-1, may be added to the cell surface of the tumor cells by inserting the gene coding for it into the genome of the tumor cell. We have demonstrated with cell culture studies that RCC cells may be effectively maintained and expanded in culture, and that if then infected with an adenovirus which has been modified to carry the B7-1 gene, will express this immune system stimulating protein.

In the proposed study, we will collect tumor specimens from eligible patients who have consented, and will place them into culture. We will then, using the adenovirus system, introduce the gene for B7-1 into the cells and then freeze them. When thawed, the cells will be used as a vaccine in the patient from whom they were derived.

The purpose of this study is threefold. First, to find out, by giving increasing numbers of vaccines to patients in successive groups of five, whether there is an upper limit to how many B7-1 expressing tumor cells may be injected. Second, to follow the vaccinated patients and determine if the vaccine has been effective at reducing their disease. Finally, to examine patient specimens for evidence of stimulating an immune response.