

Non-technical
Abstract

This is a clinical research study for patients with advanced prostate cancer. Some prostate cancers seem to grow because problems occur in a part of the cell that usually stops cancer. This part is a gene called p53. In this study, normal p53 genes will be put into cancer cells to try to stop the cells from growing. Such treatment is called gene therapy. Tumors in the prostate will be directly injected with a gene therapy known as Ad-p53. The injections will be done through the rectum using a machine which shows a picture of the area to the treating physician called ultrasound. The ultrasound is used to guide the needle to the prostate. At the time of the treatment, the physician will obtain tissues (biopsies) of the prostate. The tissue will be tested for cancer cells and various other tests. All patients will receive at least one course of Ad-p53 treatment. In each course, Ad-p53 will be given once every 2 weeks for 6 weeks (a total of 3 doses). Some patients may receive up to 2 more courses of treatment, depending on the tumor response.

After treatment is complete, surgery will be done to examine the prostate and remove lymph nodes in the area. If cancer has spread, the prostate will not be removed. If cancer has not spread, the prostate will be removed.

Tumor samples will be taken to see how the tumor responds to treatment. Patients will be examined for adverse effects of the treatment throughout the study. Urine, blood and fecal samples will be examined for evidence of the treatment (Ad-p53). An MRI will be done every 8 weeks. Patients will be examined every 3 months after they discontinue treatment.