

**Precis**

This trial will evaluate the immunologic effects of a vaccination regimen in HLA-A2 positive prostate cancer patients. Eligible patients will have localized prostate cancer and be willing to undergo definitive local radiotherapy. 30 patients will be randomized in a 2:1 ratio into two groups (see schema below) with patients in the vaccine arm receiving vaccination before, during and after primary standard radiotherapy (external beam alone or in combination with brachytherapy). The vaccine regimen will be composed of (1) a recombinant vaccinia virus that expresses the Prostate Specific Antigen gene (rV-PSA), admixed with (2) a recombinant vaccinia virus that expresses B7.1 costimulatory molecule (rV-B7.1); followed by (3) sequential vaccinations with recombinant fowlpox virus containing the PSA gene (rF-PSA). All patients on the vaccine arm will in addition receive GM-CSF and IL-2 as part of their vaccination schedule.

The primary endpoint is to identify immunologic response as measured by *in vitro* analysis of the patients peripheral blood cells. The immune response of the two arms will be analyzed at various times to determine whether a specific immune response can be effected by the vaccination as well as whether radiotherapy has an effect on that immune response. The serum PSA will be followed as a secondary endpoint.

All patients with PSA-expressing adenocarcinoma of the prostate will be evaluated for eligibility that includes a history of prior vaccinia (as vaccine against smallpox) and immunocompetence.