

Non-technical abstract for protocol "Adenovirus p53 Infected DC Vaccine for Breast Cancer".

This is a phase I-II trial designed to determine the safety and immune effects of a novel vaccine in patients with no previous chemotherapy and a newly diagnosed stage II or III breast cancer that over-expresses the protein p53. Eligible patients may have had a lumpectomy and axillary dissection or mastectomy showing disease in four or more positive nodes. Patients with tumors that measure at least 3 centimeters in the breast and/or have axillary lymph nodes more than 1 centimeter and will be treated with chemotherapy before lumpectomy and axillary dissection or mastectomy are also eligible. All patients will be treated with the same chemotherapy of cyclophosphamide and Adriamycin every three weeks for four cycles followed by 12 weeks of weekly Taxotere and radiation. All patient will receive a vaccine made from cells collected from their peripheral blood that are cultured with cytokines to form cells particularly effective in presenting proteins to the immune system called dendritic cells. The dendritic cells are infected with non-replicating adenovirus that contains p-53 allowing the dendritic cell vaccine to present p-53 to the immune system in the hopes of stimulating an immune response directed at the p53-containing breast cancer cells. Patients will be randomized between two schedules of vaccine administration. Patients on schedule A will receive three vaccines during their chemotherapy and radiation and the fourth vaccine 12 weeks after radiation therapy. Patients on schedule B will receive vaccine every two weeks starting six weeks after the end of radiation. Blood samples will be studied for determination of the humoral and cellular immune response to p53.