

Abstract- non-technical- A **PILOT** STUDY OF SEQUENTIAL VACCINATIONS WITH RECOMBINANT VACCINIA-CEA(6D)-TRICOM, AND RECOMBINANT FOWLPOX-CEA(6D)-TRICOM (B7.1/ICAM-1/LFA-3) WITH SARGRAMOSTIM (GM-CSF), IN CONJUNCTION WITH STANDARD ADJUVANT CHEMOTHERAPY IN HIGH RISK BREAST CANCER PATIENTS STATUS POST SURGERY WITH 4+ OR MORE LYMPH NODES AND CEA EXPRESSING TUMORS.

Patients with breast cancer who have 4 or more positive lymph nodes at time of surgery have a very aggressive form of disease. It often causes a red, swollen, tender breast. Standard treatment includes a combination of chemotherapy, breast surgery and radiation. Despite the best treatments with standard chemotherapy, only 35% -40% of patients with will be alive without breast cancer. We would like to improve upon these results. To try and develop a better treatment this disease, we have developed a pilot research study using a new investigational vaccine in combination with standard chemotherapy (cancer fighting drugs) to be given following surgery for women with stage II and stage III breast cancer with 4 or more positive lymph nodes. This investigational vaccine attacks cancer cells containing a protein called CEA. CEA is a protein target that is seen in almost all cancers of the colon and rectum. It is also a target for this vaccine in most breast cancer (approx. 60%). For eligibility purposes, we will look cells from a patient's tumor to see if they contain the CEA target. We will also draw a blood test to see if you have increased amounts of CEA.

Also as part of the initial evaluation to determine if a patient is eligible for the study, we will test a patient's blood for tissue type. This is the kind of blood test that is done when people are tested to see if they are a match for organ donations and is similar to finding out a person's blood type. A person's tissue type, or HLA (human leukocyte antigen) type, can influence how the immune system recognizes certain targets. Thirty to 50% of individuals are a type called HLA-A2. We currently have the ability to perform blood tests on those patients who are HLA-A2 positive to see if the vaccine is having a positive influence on these patients' immune cells. All patients will receive the vaccine (experimental therapy) as well as chemotherapy (Standard Care). Patients will be treated with either one of two treatment regimens using the vaccine and chemotherapy. The decision to treat individuals with one treatment or the other will be decided by randomization, which is performed by a computer but is similar to a choice determined by a flip of a coin. Patients randomized to treatment A will receive vaccine prior to beginning, during, and following the completion of chemotherapy. Patients randomized to Treatment B will receive vaccine prior to beginning and following the completion of all chemotherapy, but not during the chemotherapy treatment. Chemotherapy will last approximately 6 months. The purpose of this research is to evaluate how well your immune system improves against the CEA target comparing two vaccine regimens upon the completion of the chemotherapy.