

PROVIDING ENGINEERED T CELLS (PET): THERAPY FOR CANINE LYMPHOMA

TRIAL 1.1

AUTOLOGOUS T CELL INFUSION IN CANINES WITH B-LINEAGE LYMPHOID MALIGNANCIES



I. Canine Lymphoid Malignancies

One million domesticated dogs in the United States will be diagnosed with some form of cancer this year. Cancer is the number one overall cause of death for dogs. They develop many of the same cancers as humans. Interestingly, canine cancers share many similarities with human cancers. Canine tumors, like human ones, may develop resistance to treatment and metastases. Thus, canine tumors serve as a model for human tumors.

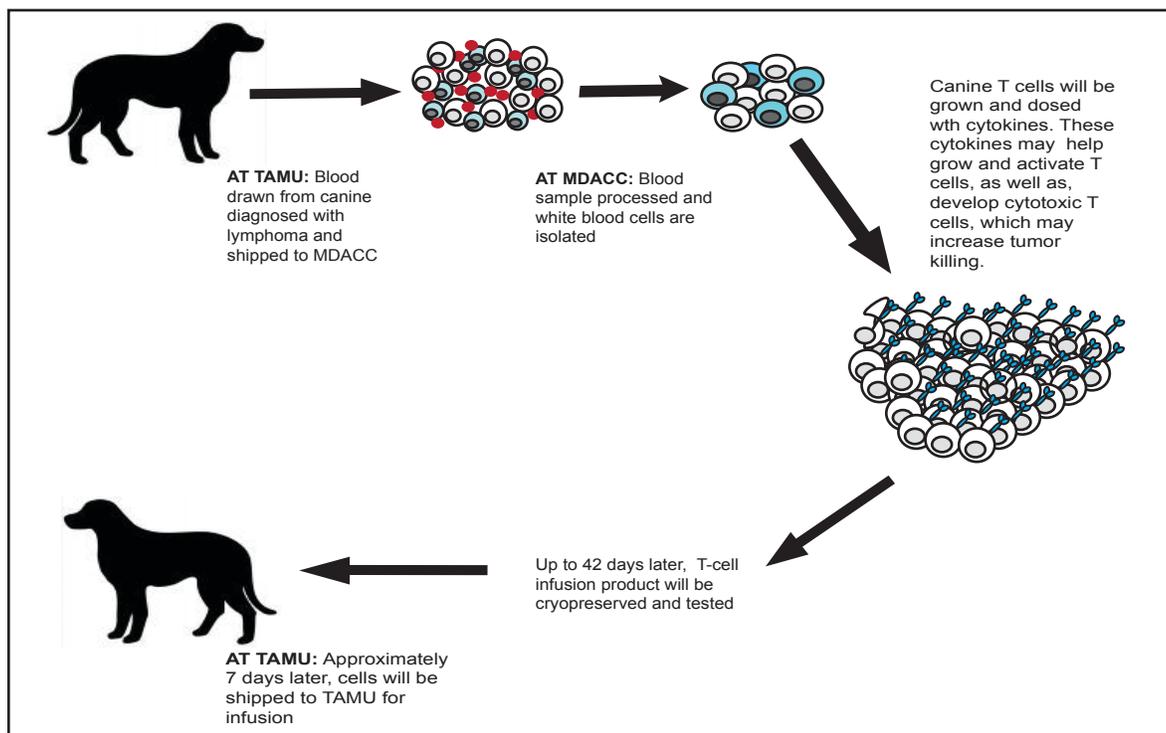
II. PET 1.1 Objectives

Unfortunately, the management of cancer in canines and some humans is limited. The primary objective of this study is to develop novel treatments for canine lymphoma using gene and immunotherapies, there by addressing the growing needs of canines with this refractory cancer. Furthermore, the information gathered from this trial will help us to create better immunotherapies for children and adults with lymphoma.

III. Adoptive Immunotherapy with T cells

T cells are white blood cells or lymphocytes that mature and develop in the thymus. After maturation, T cells circulate through the blood and lymph nodes on patrol for tumor cells. They also play a major role in the immune system's ability to recognize and fight infections. However in some diseases, like cancer, the T cells ability to recognize and attack tumor cells is impaired. Adoptive immunotherapy with T cells describes the ability of T cells to be isolated from a blood sample, grown, and given back into the donor. **Figure 1** details the process. Using T-cell therapies to fight lymphoid malignancies may provide long-lasting and possibly permanent remissions, by increasing a continuous tumor specific immune response that can patrol through the body. Biological therapies, such as infusing T cells, target tumors using mechanisms that do not rely on or act like traditional chemo and radio-therapies.

**Figure 1:
PET 1.1
Therapy
Schematic
Diagram**



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IV. Inclusion Criteria

Any dog with active lymphoid malignancies

V. Exclusion Criteria

Any canine too ill to proceed in the opinion of the veterinarian; canines with known allergies to bovine or murine products; or the inability to manufacture T cells.

VI. Possible Side Effects

The effects of infusing T cells in canines is unknown. However, adverse effects associated with human T-cell infusions seldom occur and if they do occur, are short-lived.

VII. T-cell Therapy

At trial enrollment, 10-20 mL of blood will be drawn from the canine and shipped to the University of Texas M.D. Anderson Cancer Center for T cell culturing. The anticipated time to infusion is up to 42 days, during which time the canine will receive a standard of therapy recommended by the veterinarian. There may be up to 5, T-cell infusions over 4 to 8 weeks, with each dose increasing. The infusions will take place at Texas A&M University Veterinary School. To help our trial succeed, we ask for the the dog to be available for follow up after each infusion. The veterinarian will provide details. Owners may be contacted by the CooperLab at the M.D. Anderson Cancer Center for up to 1 year post infusion for follow-up information on the health and status of the canine.

VIII. Cost

The manufacture and infusion of T cells is free.

If you wish to enroll, please speak with TAMU veterinarian, Dr. Heather Wilson, DVM, DACVIM. If you have further questions you may contact, Dr. Colleen O'Connor, Ph.D. at M.D. Anderson Cancer Center, through email: coconnor@mdanderson.org, phone: 713-792-0485, or address: The University of Texas M.D. Anderson Cancer Center, Experimental Pediatrics, 1515 Holcombe Blvd. Unit 907, Houston, TX 77030-4009

Thank you for your cooperation and participation in **Making Cancer History®!**