A Multicenter, Randomized, Placebo-Controlled Study of Monoclonal Antibody Therapy in Combination with CCNU Chemotherapy in the Treatment of Canine T-cell Lymphoma

Purpose

To determine if treating dogs with T-cell lymphoma using chemotherapy plus a monoclonal antibody will prolong remission time, increase duration of response to chemotherapy, and prolong overall survival

Background

Canine lymphoma is the most common cancer diagnosed and treated in veterinary practice. Frequently, the first and/or only detected abnormalities are enlarged, non-painful lymph nodes, and most dogs are asymptomatic at presentation. Commonly used treatments for canine T-cell lymphoma include multi-agent chemotherapy and single agent chemotherapy such as CCNU.

In this study, we're testing whether the addition of a monoclonal antibody can improve outcomes for dogs with T-cell lymphoma. Based on results of a preliminary safety and efficacy study, this antibody was conditionally licensed by the USDA for the treatment of canine T-cell lymphoma. We're now seeking to discover if treating affected dogs with chemotherapy combined with the monoclonal antibody will prolong remission time, increase response duration, and prolong overall survival.

Eligibility

- Written owner informed consent obtained prior to screening the dog
- Age > 1 year and body weight ≥ 5 kg
- Biopsy and flow cytometry confirmation of intermediate or high grade T-cell lymphoma of Stage II or higher
- At least one peripherally located lymph node measuring ≥ 2 cm longest diameter
- Performance Score of 0, 1, or 2 [0 = normal activity; 1 = restricted activity: decreased activity from pre-disease status, 2 = compromised, ambulatory only for vital activities, consistently defecates and urinates in acceptable areas]

Exclusion Criteria

- Glucocorticoid therapy administered for more than 7 days prior to enrollment
- Prior chemotherapy, immunotherapy, or molecular-targeted therapy
- ALT ≥ 2x upper limit of normal
- Any uncontrolled medical condition (including other concurrent malignancy) that may disrupt study intent and objectives
- Dog is pregnant or likely to become pregnant
- Dog is participating in another study
- Dog may not be available for the entire study duration

Study Design

All enrolled dogs will initially be treated with standard CCNU chemotherapy. At Week 6 of the study, dogs will be randomized into experimental and control groups (50:50 ratio). To ensure the accuracy of the study findings, your veterinarian will be “blinded,” i.e. they will not know which group your dog is in. The monoclonal antibody or placebo will be initiated and administered twice weekly for 4 weeks and every other week for 4 additional treatments. The antibody is administered as an IV infusion over 15-30 minutes. In the event that your dog's lymphoma progresses past a threshold designated by the protocol, your dog will be removed from the study and will be eligible to receive another treatment as recommended by your veterinarian. All study related treatments and rechecks will take place at the Veterinary Teaching Hospital on the VirginiaTech campus in Blacksburg, VA.

Compensation

Once informed consent is obtained and the patient is enrolled, this study provides partial funding for screening and full funding during the study period for all study-related costs, including study visit evaluations and all necessary diagnostics and treatment. The study will provide a maximum of $1,200 in compensation for management of adverse events and supportive medications during the study.
Additional adverse event or medication costs will be owner financial responsibility once $1,200 is surpassed. In the event that the $1,200 is not surpassed and your dog experiences progressive disease during the course of the study, the remainder of the $1,200 may be applied towards additional oncology care for your dog.

Contact

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If your query is urgent, please call the Small Animal Hospital (540) 231-4621 and ask for the oncologist on duty.