



Funded Study: Treatment of Lymphoma and Solid Tumors (non-sarcomatous) in Dogs

University of Illinois Cancer Care Clinic and Comparative Oncology Research Laboratory

Study Title: COTC027 - Preclinical Comparison of Two Hypomethylating Nucleosides in Tumor-Bearing Dogs

Purpose of Study: To establish the safety, tolerability, and maximum tolerated dose (MTD) of oral drugs (TdCyd and Aza-TdC) that can alter gene expressions when administered daily for 5 days a week for 2 weeks, with one week off, q 21-day cycles, to canine patients with refractory or treatment-naïve high-grade lymphoma or non-sarcomatous solid tumors. The effects of treatment on tumor gene expressions will be evaluated using genomic and protein detection methods. In addition to monitoring changes of tumor gene expressions at the site of bodily involvement (lymph node or other site), similar changes will be characterized in tumor cells found in the blood circulation in some patients. The clinical trial in tumor-bearing dogs is intended to define the safety, pharmacokinetics, and pharmacodynamic modulation of these investigational agents. This is designed as a dose escalation trial wherein tolerability, clinical efficacy, and pharmacokinetic/pharmacodynamic data is collected in canine high-grade lymphoma and non-sarcomatous solid tumors. Study objectives are to distinguish the toxicity profiles of these agents and to determine a difference in biological activity if one exists in pet dogs receiving treatment.

Inclusion Criteria:

- Dogs with confirmed (cytology or histopathology) of lymphoma or a solid tumor (non-sarcomatous)
- Lymphoma must be stage 2 or greater with at least 3 lymph nodes greater than 3cm (longest length)
- Solid tumors must be accessible for biopsy and measure at least 3cm (longest length) with an accessible draining lymph node
- Dogs must have a favorable performance status and both newly diagnosed and recurrent disease are eligible

Eligibility Diagnostics:

Prior to study entry, pet owners will be charged an initial consultation fee and be financially responsible and required to have the following diagnostics performed in their dog:

- 1) Diagnosis of lymphoma or a solid tumor (non-sarcomatous) with histopathology or cytology, if not already documented
- 2) Screening blood work and urinalysis, if not performed within 7 days

Treatment:

Within this study, we ask that serial biopsies of the dog's tumor is permitted. A biopsy will be collected prior to the first dose of drug (pre-treatment), on Day 8, Day 12 and possibly on Day 22 depending on how the dog has responded to therapy. Each of these biopsy sessions will occur under anesthesia, either local (sedation with anesthetic) or general. The dog will return to the Veterinary Teaching Hospital on Days 8, 12, 15 and 22. Serial blood collections (5 time points) will occur on Day 1 of the study. Subsequent, single time point collections will occur on Days 8, 12, 15 and 22. Owners will be required to administer doses of TdCyd or Aza-TdC at home on Days 2, 3, 4 and 5 and on Days 9, 10, 11. The clinician trials doctor will provide instructions on when and how to give this medication.

Compensation:

This is a partially funded study. Pet owners are financially responsible for all diagnostics such as blood work and cytology required for their pets to be deemed eligible for study recruitment. Pet owners will be responsible for any costs associated with unrelated medical conditions. After eligibility requirements have been met, patients' fees will be waived for the recheck exams, bloodwork and collection of study endpoints. After the patient has completed the clinical trial (Day 22 minimum) a \$1000 credit will be applied to the owners account for in hospital use only, and could be used for pursuit and payment of traditional therapies. The study will provide up to \$2000 for adverse event management associated with administration of Td-Cyd and Aza-TdC. You will be responsible for any costs associated with the normal course of treatment, the treatment of any complications that may arise, and unrelated medical conditions.

Contact Information:

Please feel free to contact our Clinical Trials Coordinator, Rebecca Kamerer, at (217) 300-6453 or rmoss81@illinois.edu to refer a patient or for any additional information. Referring veterinarian and client calls are welcome.

