



Funded Study: Treatment of Canine Oral Malignant Melanoma

University of Illinois Cancer Care Clinic and Comparative Oncology Research Laboratory

Study Title: Evaluating the safety and immune activation properties of collagen-anchored canine recombinant interleukin-2 and interleukin-12 proteins in tumor-bearing dogs

Funded Study: Funded study for canine patients with oral melanoma

Study Title: Evaluation of intratumoral cytokine therapy in dogs with an oral melanoma with bulky disease present.

Purpose of Study: Stimulating the immune system to fight cancer is a well-described and accepted treatment option for controlling cancer growth and metastases in people. Specific proteins called cytokines are necessary to amplify the immune response, including interleukins -2 and -12. While interleukins -2 and -12 are important for robust immune activities, when systemically released, these inflammatory proteins can lead to toxicity, sometimes severe and life-threatening. Anchoring these cytokines within the tumor mass would have the potential of harnessing the benefits of the immune system, yet reduce the changes for untoward systemic toxicities. Recent studies have shown that anchoring interleukins -2 and -12 within tumor masses is highly effective in fighting cancer and minimizing toxicity in mouse models of cancer, and our preclinical studies have demonstrated that this immune stimulating strategy can also be safely administered to healthy beagle dogs. The intent of this study is to evaluate the same technological advance in pet dogs with cancer, including soft tissue sarcomas and melanomas. The findings from the current investigation will be helpful to further the evaluation of anchored cytokine strategies as a safe and novel anticancer immune therapeutic strategy to fight cancer in pet dogs. Should you decide to enroll your pet in this clinical trial, your dog will receive 6 total treatments every 14 days.

Inclusion Criteria:

- Dogs with confirmed (cytology or histopathology) oral melanoma
- Dogs with oral melanoma measuring 1-5 cm in diameter within the oral cavity
- Dogs with adequate organ function indicated by standard laboratory tests
- NO treatment with radiation therapy or systemic chemotherapy
- NO treatment with any immunosuppressive/homeopathic/alternative therapy including prednisone, cyclosporine or other immunomodulator agents.

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 melanoma with histopathology or cytology, if not already documented
- 2) Screening blood work and urinalysis, if not performed within 7 days
- 3) CT scan of the head and chest

Treatment:

All dogs will be treated with intratumoral cytokine therapy containing anchoring interleukin-2 and interleukin-12 for a total of 6 treatments 14 days apart. Each dog will have routine bloodwork, urinalysis, lymph node aspirates (if indicated) and recheck CT scans at defined scheduled reevaluations. Following completion of intratumoral cytokine injection, dogs will be followed with physical exams and CT scans.

Compensation:

Pet owners are financially responsible for all diagnostics such as blood work and cytology/histopathology required for their pets to be deemed eligible for study recruitment. After patients have been deemed eligible, this is a fully funded trial, and all scheduled diagnostics and hospital visits will be paid for. Adverse side effect management will remain the financial responsibility of the pet owner.

Contact Information:

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

