

Funded Study: Treatment of Canine Osteosarcoma

University of Illinois Cancer Care Clinic and Comparative Oncology Research Laboratory

Study Title: Evaluation of Inhaled recombinant-human IL-15 combined with Standard-of-Care in dogs with Osteosarcoma

Funded Study: Funded study for canine patients with appendicular osteosarcoma

Purpose of Study: Pulmonary metastasis continues to be the major cause of mortality among human and canine patients with osteosarcoma (OSA). Interleukin-15 (IL-15) is a pro-inflammatory cytokine that stimulates the proliferation, generation, and maintenance of T-cells as well as Natural Killer (NK) cells. IL-15 has been found to demonstrate potent anticancer immune responses in mouse models of cancer. Subsequent human clinical trials have demonstrated IL-15 induced activation and expansion of NK cells in human patients. This study is designed to specifically determine the ability of human recombinant IL-15 (rhIL-15) to significantly delay the onset of pulmonary metastasis. The main endpoint of this study is disease-free interval, which is defined as the period between the date of surgical resection and confirmation of pulmonary and/or distant metastasis.

Inclusion Criteria:

- Dogs with confirmed diagnosis of osteosarcoma by cytology (with a positive alkaline phosphatase stain) or histopathology
- The primary tumor must be surgically resectable via amputation
- Dogs must have x-rays that confirm there is no metastatic disease and cytology confirming there is not metastasis to the regional lymph node
- NO treatment with any previous chemotherapy, radiation, immunotherapy, or bisphosphonates.
- 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 osteosarcoma with histopathology or cytology, if not already documented
- 2) Screening blood work and urinalysis, if not performed within 7 days
- 3) Chest x-rays to confirm no evidence of metastatic disease

Treatment:

Once the patient is deemed eligible they must undergo amputation at the University of Illinois within 7 days. Owners will be taught how to administer IL-15 at home where the dog will receive twice daily treatments for 14 days. The patients will return to the University of Illinois for treatment with carboplatin for 4 treatments 3 weeks apart. After the therapy is completed the patient will need to return to the University of Illinois once every 8 weeks for thoracic radiographs until progressive disease is seen.

Compensation:

This is a partially funded study upon patient eligibility and enrollment. Prior to confirmed enrollment, pet owners are financially responsible for all diagnostics such as blood work, cytology, imaging required for their pets to be deemed eligible for study recruitment. After enrollment, owners are responsible for the cost of amputation and chemotherapy visits. Pet owners will be responsible for any costs associated with the normal course of treatment. The trial will cover the cost of IL15 and the equipment used to administer the therapy. It will also cover the cost of the follow up visits and x-rays.

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.

