

Funded Study: Treatment of Canine Osteosarcoma.

Study Title: Synergizing Radiation-Induced Immunogenic Cell Death and Toll-Like Receptor 9 Agonism to Generate Abscopal Effects in Canine Osteosarcoma.

Purpose of Study: Greater than 80% of dogs diagnosed with osteosarcoma (OSA) have microscopic disseminated disease at presentation and will die from metastatic progression within 2 years of diagnosis regardless of treatment. Strong justification exists for discovering effective systemic therapies to improve outcomes in pet dogs diagnosed with OSA, and provocatively clinical evidence supports the potential for harnessing host immunity for delaying OSA metastatic progression. As such, amplifying immune responses within the primary tumor microenvironment by radiation, coupled with intratumoral administration of pathogen associated molecular patterns (PAMPs) agonists, could improve disease outcomes in dogs with OSA through the generation of potent and systemic abscopal effects.

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 chest 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 on their dog:

- 1) Diagnosis of osteosarcoma via 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/Protocol: Once the patient is deemed eligible the patient will receive 4 doses of radiation once weekly coinciding with an immune stimulating agent called CPG, which

is injected around the tumor. Four weeks after the patient will receive a limb amputation. The patient will need to return to the University of Illinois once every 8 weeks following surgery 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. Pet owners will be compensated for their animal's participation in this study. The study will partially defray costs associated with the pharmacodynamic and radiologic aspects of the project, including blood and radiologic tests, as well as hospitalization required.

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.

