

Funded Study: Funded study for canine patients with soft tissue sarcoma

Study Title: Evaluation of intratumoral cytokine therapy in dogs with surgically resectable soft tissue sarcoma.

Purpose of Study

Soft tissue sarcoma is a collection of common tumors arising from the soft tissue structure of the body. Most often, soft tissue sarcoma affects the body or legs of affected dogs, and these tumors can grow large and become painful or infected, ultimately necessitating surgical removal. In a small proportion of dogs with soft tissue sarcomas, there can be spread of disease to other parts of the body, which requires systemic therapies (chemotherapy). Over the past 10 years, there has been increasing interest in fighting cancer with the body's own immune system, and this is called immunotherapy. The intent of this study is to investigate an immunotherapy strategy that injects immune stimulants into the local tumor growth of dogs with soft tissue sarcomas. This study will evaluate the immune activating abilities, safety, and potential therapeutic effectiveness of intratumoral anchoring interleukin-2 and interleukin-12 cytokines for treatment of soft tissue sarcoma.

Inclusion Criteria

- Dogs with confirmed (cytology or histopathology) soft tissue sarcoma
- Dogs with soft tissue sarcoma measuring 1-6 cm in diameter, and amendable to surgical removal
- NO treatment with radiation therapy or systemic chemotherapy a minimum of 3 weeks prior to study entry
- NO treatment with any commercial non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, or immune modulating drugs (cyclosporine, etc) for the duration of study (4 weeks)
- Kidney parameters (creatinine) and liver parameters (ALT) no greater than 1.5x of upper normal limits prior to study entry
- Signed informed client consent

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 soft tissue sarcoma with histopathology or cytology, if not already documented
- 2) Screening blood work and urinalysis, if not performed within 7 days
- 3) Mass must be amendable to complete or marginal excision

Treatment

All dogs will be treated with intratumoral cytokine therapy containing anchoring interleukin-2 and interleukin-12 for 2 consecutive treatments 14 days apart. Two weeks following the second dose of immunotherapy, dogs will have soft tissue sarcomas surgically resected. Each dog will have routine bloodwork, urinalysis, lymph node aspirates and tumor biopsies at defined scheduled reevaluations.

Compensation

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. After patients have been deemed eligible, this is a partially funded trial, and all scheduled diagnostics and hospital visits will be paid, in addition a \$2000.00 in hospital credit will be applied towards surgical removal of the soft tissue sarcoma.

Contact Information

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