ILLINOIS

College of Veterinary Medicine
Veterinary Teaching Hospital
1008 W. Hazelwood Drive
Urbana, IL 61802

Funded Study: Canine soft tissue sarcoma amenable to surgical removal

Study Title: Evaluating the safety and immune activation properties of JEN-101(anchored interleukin-12) following intratumoral injection in dogs with spontaneous cancer

Purpose of Study/Background/Objectives: Stimulating the immune system to fight cancer is a well-described and accepted treatment option for controlling cancer growth and metastasis in people. Specific proteins known as cytokines are essential for amplifying the immune response; however, certain cytokines—such as interleukin-12—can be toxic when administered intravenously. Recent studies have demonstrated that anchoring interleukins within tumor masses can effectively enhance anti-tumor activity while minimizing systemic toxicity in both mouse and canine models. In a previous study we showed that a similar immune strategy can be given safely in dogs with naturally occurring tumors, specifically melanoma. The intent of this trial is to evaluate dogs with surgically excisable soft tissue sarcomas to evaluate that there is an immune response in the patients given JEN-101 intratumorally.

Inclusion Criteria:

- Dog with a confirmed diagnosis of soft tissue sarcoma by either cytology or histology.
- Tumors must be between 1-5 cm in diameter.
- Tumor must be amenable to marginal or complete surgical resection.

Exclusion Criteria:

- No previous radiation.
- Patients must have a 3-week washout from previous chemotherapy.
- While on study patients cannot have any immunosuppressive/homeopathic/alternative therapy including prednisone, cyclosporine or other immunomodulator agents.

Eligibility Diagnostics:

- CBC, Chemistry Panel, Urinalysis (within 28 days of starting therapy)
- Tumor confirmation via histopathology or cytology.

Treatment/Protocol:

- Dogs will receive a small biopsy of tumor followed by an intratumoral injection of JEN-101 7 days later.

- Seven days after intratumoral injection treatment, the tumor will be surgically excised. This is a 14-day study and participation is complete following surgical removal.
- This surgery MUST happen at the University of Illinois.

Owner Commitments: You are responsible for the initial exam and diagnostics to determine eligibility.

- You are expected to make and keep all appointments associated with the study.
- You are responsible for all costs associated with unrelated medical conditions.

Compensation: This is a partially funded study. The clinical trial will cover the cost of the cytokine treatment, exam fee on treatment day, biopsy charges and up to $2500 towards surgical excision. The surgery MUST happen at U of I to be part of the clinical trial.

Contact Information: Our trials team recommends you schedule an on-site appointment to assess your pet's eligibility. We do not require a referral. The professional fee for the consultation is approximately $200 and does not include tests, medications or treatments that may be recommended at your appointment. **To schedule please call 217-333-5300.**

We would like the opportunity to review your pet's records from your veterinarian. After the appointment has been made the records can be emailed to medrec@illinois.edu or faxed to 217-244-2554.

If you have further questions, please feel free to contact our Clinical Trials Coordinator, Rebecca Kamerer, at (217) 300-6453 or rmoss81@illinois.edu

Referring veterinarians and client calls are welcome

Please check our up-to-date website to see if this trial is still active and enrolling.

https://vetmed.illinois.edu/research/clinical-trials/