

Patient Disease: Canine appendicular osteosarcoma.

Study Title: Investigating the immunological effects and safety of integrating stereotactic body radiation therapy and dendritic cell homing hydrogels for the treatment of canine osteosarcoma (OSA).

Purpose of Study/Background/Objectives: Dendritic cell (DC) homing gels have been shown to be safe and effective at stimulating local immune cells at the injection site. In this trial we will be using stereotactic body radiation therapy (SBRT) along with DC-homing materials in dogs with OSA. We aim to elicit immunogenic cell death of OSA cells with SBRT and integrate with DC-homing materials for the development of potent in situ cancer vaccines. We will explore the immunological effects and safety profile of integrating SBRT and DC-homing hydrogels for the treatment of canine OSA. We are hopeful that combination therapy may be better at stimulating the immune system against the primary tumor and the development of metastatic disease. In this trial we will evaluate the combination to see if there is clinical benefit.

Inclusion Criteria:

- Dogs > 1yr of age and at least 5 kg
- Dogs with appendicular osteosarcoma that have a histologic or cytologic (alkaline phosphatase positive) diagnosis of sarcoma, consistent with osteosarcoma.
- No metastatic disease on chest x-rays and abdominal ultrasound
- No prior radiation or chemotherapy
- No previous immunotherapy. No use of Apoquel, steroids (topical or systemic) or immune modulators such as cyclosporine within 14 days.
- Adequate organ function for sedation

Exclusion Criteria:

- Metastatic disease (chest or abdomen)
- Previous radiation or chemotherapy or immunotherapy
- Significant preexisting renal, hepatic, or cardiac disease
- History of auto immune disease

Eligibility Diagnostics: Within 14 days of starting trial

- CBC, Chemistry Panel, U/A
- Cytology or histopathologic diagnosis with alkaline phosphatase positivity
- Cytology of regional lymph node if accessible
- 3 view chest x-rays
- Abdominal Ultrasound

Treatment/Protocol:

- Patients will receive a CT scan under anesthesia with tumor biopsy
- Patients will receive radiation therapy 3 days in a row followed by hydrogel injection near the tumor site immediately after the 3rd radiation dose
- Post treatment blood will be collected 4 days after radiation completion and then on weekly scheduled visits
- After radiation, rechecks will be once a week for 5 weeks and then study is complete
- Following completion of trial, patients may go on to other traditional treatments

Owner Commitments:

- You are responsible for the initial exam and diagnostics to determine eligibility
- You are responsible for pain medication costs
- 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 fully funded trial once your pet is deemed eligible
- During the treatment phase the trial will cover the cost of CT scan, radiation therapy, hydrogel injection, biopsy, recheck exams and blood work.

Contact Us: 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 \$250 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/>