

Patient Disease: Canine appendicular osteosarcoma.

Study Title: Evaluating aluminum hydroxide-anchored recombinant interleukin-12 (JEN -101) in combination with radiation therapy and amputation in dogs with appendicular osteosarcoma.

Purpose of Study/Background/Objectives: JEN-101 has been proven to work reasonably well to stimulate the immune system against canine melanoma. In this trial we will be using the same idea to treat dogs with osteosarcoma and adding in radiation therapy. We are hopeful that combination therapy may be better at stimulating the immune system against metastatic disease. In this trial we will evaluate the combination to see if there is clinical benefit.

Inclusion Criteria:

- 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 radiation or chemotherapy
- No previous immunotherapy, check point blockade treatment Apoquel, steroids or immune modulators such as cyclosporine.
- Adequate organ function for sedation

Exclusion Criteria:

- Metastatic disease
- Previous radiation or chemotherapy or immunotherapy

Eligibility Diagnostics:

- CBC, Chemistry Panel, U/A
- Cytology or histopathologic diagnosis with alkaline phosphatase positivity
- 3 view chest x-rays (within 14 days of starting trial)
- Abdominal Ultrasound

Treatment/Protocol:

- Patients will receive radiation therapy for the affected leg followed by an injection of JEN-101 in the tumor 2 days and 2 weeks after radiation
- On visits for JEN-101 treatment blood will be collected over 24hrs. Patients can either stay in hospital or return the next day for a blood draw
- Four weeks after radiation therapy the leg will be amputated, and samples will be collected
- After surgery, rechecks will be once every 8 weeks long term, if patient does not go onto standard therapy once progressive disease is noted.
- We will use complete bloodwork, chest x-rays every 2 months, abdominal ultrasound every 4 months, and study blood samples to track patients' responses.

Owner Commitments:

- You are responsible for the initial exam and diagnostics to determine eligibility
- You are responsible for exam and blood work costs for recheck visits
- You are expected to make and keep all appointments associated with the study
- You are responsible for the cost of amputation, must be done at U of I
- You are responsible for all costs associated with unrelated medical conditions

Compensation:

- This is a partially funded trial once your pet is deemed eligible
- During the treatment phase the trial will cover the cost of radiation, JEN-101 and the associated charges at those visits
- During the recheck phase the trial will cover the cost of abdominal ultrasound and chest x-rays
- Up to \$2500 of the cost of amputation is covered when done with the U of IL.

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 \$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/>

