Veterinary Health Center
AT KANSAS STATE UNIVERSITY
TO DISCOVER. TO TEACH. TO HEAL.

Study Title

Study to use MT0321 as a Radiation Sensitizer for Dogs with stage III and stage IV nasal adenocarcinoma undergoing palliative radiation therapy

Why are we doing this study?

We propose to investigate the benefit of a new radiation sensitizer (MT0321) against spontaneous canine malignant tumors when it is combined with palliative radiation therapy. Radiation therapy is a gold standard to treat nasal tumor in dogs. The goal of palliative radiation therapy (PRT) is to shrink or stabilize the tumor to make the patients comfortable. The new radiosensitizer was derived from marine organisms as a natural product is proposed to sensitize tumor cells to radiotherapy by improving temporally hypoxia in tumors.

In this study standard clinical palliative radiation therapy protocol will be given with or without radiation sensitizer (MT0321). Patients will be anesthetized by a standard clinical anesthesia protocol for radiation therapy. Regular post PRT recheck will be performed in 4 weeks (Day 22 ±5 days) and 13 weeks (Day 85 ±5 days), and every 2-3 months thereafter.

Is your dog eligible?

Dogs with a stage 3 or stage 4 nasal adenocarcinoma undergoing a standard course of palliative radiotherapy (4Gy x 5 daily fractions). The dogs need to be otherwise in good health condition so that they can be followed up to 13 weeks post-radiotherapy. No prior chemotherapy, radiotherapy, or surgical therapy for the tumor are accepted.

What does this study involve?

This is a multicenter, randomized, double-blind, placebo-controlled, pilot clinical study comparing primary radiotherapy vs. radiotherapy combined with MT0321.
Dogs will be randomly assigned to one of two groups:

Group 1) Dogs will receive intravenous injection of MT0321 prior to each radiotherapy session.
Group 2) Dogs will receive intravenous injection of placebo (normal saline) prior to each radiotherapy session.

Assessment of quality of life by the owner will be done weekly at Weeks 1 to 13.

Week 1 (5 days Monday to Friday): Radiotherapy daily with or without MT0321
Dogs will receive daily injection of MT0321 or placebo intravenously 15-30 minutes prior to each radiotherapy session (therefore total 5 injections through a catheter).

Week 4 and 13: Physical examination, routine laboratory works (CBC, chemistry panel) will be performed to assess acute radiation side effects and organ function such as kidney or liver damage.

Primary Endpoint: Week 13 post recheck CT will be performed to assess tumor response to the treatment

After the primary endpoint at week 13, dogs are rechecked regularly by the Oncology Service as regular patients.

Client compensation

The compound will be provided free of charge and there is no fee associated with your participation in this study. The study covers recheck visits on the week of 4 and 13. Financial coverage includes recheck examination fee, CBC and chemistry panel for both visits and the CT scan on the week 13. Complications associated with the compound is not anticipated, but treatment for compound related complications will be covered up to $500 per individual medical needs.

The owner is responsible for all costs including exam, diagnostics, and palliative radiation therapy or any procedures performed that are not part of this study. As an incentive to participate this study, owners will receive a 20% discount for most procedures/services associated with cancer treatment (e.g., anesthesia, radiation, etc.) for those appointments which correlate with study visits (Days 0-4 and both follow up visits).

Client Responsibilities

- Come to the Veterinary Health Center for daily PRT and study drug treatment (Week 1);
- Return to the Veterinary Health Center for Week 4 and Week 13 assessments (physical examination and routine bloodwork and CT recheck at Week 13);
- Assessment of quality of life by the owner will be done weekly at Weeks 1 to 13;

Contact Information

Please contact the clinical trials coordinator at the Veterinary Health Center for more information. clinicaltrials@vet.k-state.edu or (785) 532-3046