



Funded Study: Treatment of dogs with metastatic cancer to lung, with hypo-fractionated radiation and anti-PD-1 canine monoclonal antibody.

Study Title: Optimizing hypo-fractionated radiation to maximally harness the immunogenic potential of anti-PD-1 canine monoclonal antibody for oligometastatic cancer.

Purpose of Study: Dogs who develop lung metastasis from cancer elsewhere in the body often have few to no effective treatment options. Recent clinical research in people supports better outcomes when radiation is combined with systemic chemotherapy or immunotherapy. The purpose of this clinical trial is to treat dogs with oligometastasis (5 or fewer lung masses) with radiation to those lesions plus a new immunotherapy designed for dogs that will allow the immune system to “see” the cancer cells after radiation, hopefully enhancing the effect of the radiation treatment. All dogs receive both radiation and immunotherapy. Dogs will be randomized to one of two different schedules of radiation to learn whether one provides a stronger signal to the immune system than the other.

Inclusion Criteria:

- Canine patients with a prior diagnosis of cancer that metastasizes to lung and a finding of 1-5 lung masses on 3 view chest xrays.
- Dogs must be older than 1 year and weigh at least 8 kgs.
- No current chemotherapy, immunosuppressive/homeopathic/alternative therapy/steroids/NSAIDs or cyclosporine.
 - Cytopoint for allergy treatment is allowed but Apoquel is not.
- Histopathology must be available and 5 unstained slides sent to the clinical trials team.
- If the diagnosis of the primary tumor is confirmed only by cytology and the primary tumor is still present, a small biopsy will be performed to obtain histopathology.
- Dogs must have adequate organ function.
- Respiratory rate < 60 breaths per minute at rest, no abdominal effort.

Exclusion Criteria:

- > 5 pulmonary metastatic lesions.
- No histopathologic diagnosis or inability to obtain histopathology prior to enrollment.
- Dogs < 8 kg in size and < 1 yr. of age.
- Patients lacking a confirmed cancer diagnosis or lack of slide availability.
- ANY prior immunotherapy or any radiation therapy within the last 6 mo.
- Patients taking NSAIDs or steroids. Patients can washout for 7 days prior to trial enrollment.
- Significant uncontrolled co-morbid illness, which includes but is not limited to renal or hepatic failure, history of congestive heart failure or DCM
- Tachypnea (>60 breaths per minute and/or consistent abdominal effort) at rest.
- Pleural effusion
- Previous radiation to lung
- Known aminoglycoside allergy.

Eligibility Diagnostics:

- Physical examination
- CBC, serum biochemistry, urinalysis
- 3 view chest x-rays

Treatment/Protocol: Dogs will be treated with one of two radiation protocols (10 Gy per fraction/dose). Either radiation every other day for 3 doses or radiation every other week for 3 doses. Additionally, they will receive an infusion of immunotherapy every other week for 3 doses, then once monthly for a total of 8 doses. Monitoring will occur with chest x-rays at 1, 3, and 6 months and then every 3 months thereafter. Blood will be collected to test the immune system during the treatment phase.

Compensation:

You will have costs from your animal's participation in this study, enrollment diagnostics, CT scan, chest x-rays, blood work and radiation therapy. The trial covers the cost of immunotherapy (Gilvetmab). You will be responsible for any costs associated with the normal course of treatment for unrelated medical conditions, the treatment of any complications that may arise.

Contact Information: Please feel free to contact our Clinical Trials Coordinator, Rebecca Kamerer, at (217) 300-6453 or rmos81@illinois.edu to refer a patient or for any additional information. Referring veterinarian and client calls are welcome.

