Gastrointestinal permeability in dogs with bone tumors receiving Carboplatin

Purpose and Brief Explanation of Study:

Gastrointestinal toxicity (GI) is a common side effect of cytotoxic chemotherapy administration primarily due to apoptosis of rapidly dividing enterocytes. Consequences include, treatment delays, dose reductions, impaired quality of life, increased expense, discontinuation and poorer patient outcomes. Severity of GI toxicity varies greatly, ranging from mild to severe. Measurement of Cytokeratin 18 (CK18), an intracellular structural protein released during epithelial apoptosis, and Alpha1-Proteinase Inhibitor (α1-PI) in feces provides a non-invasive mechanism for evaluation of compromise to intestinal mucosa integrity. Evaluation in these biomarkers as predictors for chemotherapy induced GI toxicity have been described in human cancer patients, but little is known about their utility in tumor-bearing dogs. The purpose of the trial is to identify non-invasive biomarkers that may help us predict patients at increased risk for chemotherapy induced gastrointestinal mucositis, and offer them more aggressive prophylactic treatment and supportive care to limit the impact on quality of life and treatment outcome.

What qualifies my dog for enrollment in this clinical trial?

Eligible patients (any breed of dog) must meet all of the following criteria:

- Dogs must have a diagnosis of a bone tumor (osteosarcoma) involving a limb.
- The owner must be willing to pursue amputation followed by chemotherapy (carboplatin x 4 doses).
- Dogs must be greater than 1 year of age and weigh at least 5 kg.
- No vomiting or diarrhea 2 weeks prior to enrollment.
- No evidence of pulmonary metastatic disease.
- Dogs must have adequate organ function as indicated by standard laboratory tests (complete blood count, serum biochemistry profile, urinalysis).
- Dogs must be medically healthy with no clinically significant physical findings upon examination, medical history, and clinical laboratory profile.

What does enrolling my dog in this clinical trial involve?

This is a prospective clinical trial for dogs with appendicular osteosarcoma that have undergone an amputation and will be receiving carboplatin. Whole blood will be collected from your dog at the designated study visits for plasma CK18 levels. You will be required to collect a fecal sample from your dog and bring it with you at the designated study visits. Study visits will occur on day -14, 0, 7 and 21 of the study. Owners will be responsible for maintaining an owner diary throughout the study to document clinical signs associated with gastrointestinal mucositis.

Client Compensation

You are responsible for all standard of care procedures performed prior to and including amputation. Following this there are no additional costs to you associated with enrolling in the clinical trial. The costs of the first and second carboplatin chemotherapy, maropitant, chemotherapy administration and PCCBC will be covered.

Following conclusion of the study (at day 21), any additional treatment that you elect to pursue will be your financial responsibility. This means that you will be responsible for all costs associated with carboplatin treatment # 3, carboplatin treatment # 4, and re-staging costs. If your dog develops toxicity associated with the administration of carboplatin at any treatment visit (carboplatin # 1 - 4) you are responsible for the cost associated with supportive care. You are responsible for the cost of supportive medications that will be discharged following each chemotherapy treatment to be used if needed.

If you believe your pet may be eligible to enter this study, please fill out a pre-screening questionnaire.