



Effects of a new highly palatable, complete, and balanced diet for canine cancer patients

Study Purpose: Malignant tumors in dogs and associated anti-cancer treatments may or may not be associated with changes in appetite. The purpose of this study is to evaluate the palatability (tastiness) and biochemical effects of feeding a newly developed, complete and balanced diet for dogs with different forms of malignant cancer who are currently undergoing conventional anti-cancer therapy and are reported by their owner to have a normal or decreased appetite.

Brief Study Description: If your dog is eligible and you decide to participate in this trial the following will take place:

Study Day 0 (Time of enrollment at KSU VHC):

- We will first have you sign and date the consent form agreeing to participate in the trial.
- The study veterinarian will perform a physical examination to confirm eligibility in the study.
- Blood will be drawn and submitted for diagnostic testing (e.g., Complete Blood Count and Chemistry). The procedures will be performed using a standard protocol.
- After the in-house diagnostics are completed and the patient is confirmed to be eligible, we will review with you, the Pet Parent Packet containing important study information, including the diet and instructions on how to feed during the trial.
- You will be required to complete forms regarding your pet's eating habits and stool using an app downloaded to your phone. The Pet Parent Packet also contains information about the VISION ePRO app and completing the forms. We will have you download the app during the enrollment visit.

Study Day 1-7 (Diet Transition):

- You will transition your dog from his/her current diet to the study provided diet using the feeding guide found in the Pet Parent Packet.

Study Day 8, 9, 10, 14, 21, 28 and 56 (At Home Reporting By Owner):

- You will record the amount of food consumed by your pet at one meal on each of these days through a form in the ePRO app.
- Additional forms assessing the stool of your pet and your pet's quality of life will be completed in the ePRO app as well.

Study Day 54 to 58 (Study Completion):

- Between days 54 and 58, you will be required to return to KSU VHC for study completion procedures, including physical examination and blood draw for diagnostic

- testing.
- You will be reminded before the visit to return any unused (unopened) bags of food.

Study Eligibility:

Inclusion Criteria

- Adult dogs, at least 1 year of age;
- Dogs with malignant cancers that are undergoing conventional treatment;
- Dogs accustomed to eating a dry kibble and with a normal or decreased appetite at the time of enrollment;
- Owner must have a working email address for communication during clinical trial participation;
- Owner must have a smartphone that is 4 years of age or younger and consent to downloading requested app onto phone and to text messaging (owners will not be reimbursed data cell phone charges, if applicable, while on study).

Exclusion Criteria

- Dogs with complete anorexia (lack or loss of appetite) and/or clinical evidence of dehydration;
- Dogs with a disease condition requiring medication other than an ongoing NSAID for arthritis, steroids, any anti-cancer medication(s)/treatment should be excluded. Specifically, conditions that should be managed with therapeutic foods and/or medications such as renal disease, heart disease, inflammatory bowel disease should be excluded;
- Dogs with a history of chronic pancreatitis or an active acute episode of pancreatitis at enrollment;
- Dogs with a history of complete surgical excision of their tumor with appropriate margins;
- Dogs that are pregnant or likely to become pregnant during the trial period.

Client Compensation: The study funds will cover the costs of the physical examinations and bloodwork required for the study. The study test diet as well as a feeding scale (necessary for measuring and recording food consumption while on study) will be provided to owners at no cost. Owners may keep the feeding scale after study participation. Owners will be responsible for the costs for tests and/or diagnostics that are not part of this trial including staging prior to enrollment as well as any treatments and/or complications associated with the underlying disease(s) that occur during the study.

Owners will receive a completion incentive for their efforts in order to maintain protocol compliance for the required study procedures. Owners will receive a \$600.00 one-time payment, if all feeding requirements and surveys are completed and all data has been collected. Compensation will only be provided if all data is collected, as required, through Day 56 Visit. Dogs that are withdrawn from the study, for any reason, will not receive compensation.

Owner Responsibilities (*owner agrees to the following*):

- Download the necessary app on their mobile device to allow for data collection during the study.
- Complete the study forms on the app on the days that they are required.
- Return to KSU VHC for the study completion visit (between days 54 and 58).
- Feed their dog the study food as directed (weighing food daily) and not exceed 10% of daily caloric intake in additional treats.
- Report any adverse events experienced by their dog while on study to the study veterinarians.

- Allow their pet to be photographed for study purposes. These photos may be used for educational papers, presentations, and/or promotional purposes by the study sponsor or the KSU VHC.
- Provide the study with their contact information in order to download and gain access to the ePRO mobile phone app.

Contact Information:

Please contact Kris Richardson, Clinical Trials Coordinator at the Veterinary Health Center, for more information about this study. Phone: (785)-532-3046; email: ClinicalTrials@vet.k-state.edu