Probiome Canine Bladder Cancer Clinical Trial

The purpose of this study is to determine if the addition of a probiotic (Escherichia coli Nissle 1917(EcN)) can improve clinical outcomes when paired with a standard-of-care therapy (vinblastine/piroxicam) for canine bladder cancer - also known as urothelial carcinoma.
To determine eligibility for this study, a basic screening visit including a physical exam, blood work, chest X-rays, a fecal exam for parasites, urinalysis, and potentially a genetic test for breeds (shepherds, sheepdogs, collies, old English sheepdogs) at high risk for carrying a mutation that increases the risk of side effects with some chemotherapy drugs will be conducted. All dogs enrolled will receive standard treatment for bladder cancer including vinblastine (a chemotherapeutic delivered intravenously) and piroxicam (a non-steroidal anti-inflammatory drug given daily by mouth). Half the dogs enrolled in this study will be assigned to receive a probiotic (given daily by mouth) in addition to the standard-of-care therapy.
The other half of the dogs will be assigned to receive a placebo (given daily by mouth). Dogs will then undergo a standard treatment regime that includes bloodwork weekly to monitor for low white blood cell counts and IV infusions of vinblastine every 2 weeks unless contraindicated. On the first and last day of the trial, dogs will also undergo sedation/anesthesia for ultrasound and tumor measurement, cystoscopy (visualization of the inside of the bladder), biopsy (tissue collection) from the tumor, and urine collection from the bladder. Owners will be asked to provide free-catch urine and stool samples from their dog every 2 weeks and asked to complete regular questionnaires and logs of the dog's clinical signs and behavior. Owners will also be asked to provide follow-up urine and fecal samples 8 weeks after the trial conclusion.

Client Compensation:
For dogs that meet enrollment criteria and enroll in this study, screening, and subsequent medical management of your dog's bladder cancer for 8 weeks or up to 4 rounds of chemotherapy will be covered at no cost to the owner/agent. The probiotic/placebo will also be provided free of charge for the duration of the study(approximately 8 weeks or for up to 4 rounds of chemotherapy). Limited funding is also available to cover adverse events secondary to the treatment protocol and in accordance with your veterinary team's recommendations. Treatment for following the conditions will be covered as part of this clinical trial during the clinical trial period: Neutropenia, urinary tract infections (UTI) and UTI workups, vomiting/diarrhea. The owner/agent is financially responsible for all veterinary costs unrelated to bladder cancer management (e.g. food, heartworm medication, medications for other conditions). Owners are also financially responsible for all costs associated with bladder cancer management beyond the trial (e.g. after 8 weeks of treatment or 4 rounds of chemotherapy) and for diagnostics and treatments associated with presumed tumor progression. Owners are also financially responsible for adverse events or injuries unrelated to bladder cancer treatment/management.

Potential Medical Benefits:
For dogs that meet eligibility criteria and enroll, screening and 8 weeks of medical management for your dog's bladder cancer will be covered by the study. Study medication is provided free of charge for the duration of the study.

Potential Medical Risks:
Risks include the potential for GI upset associated with the probiotic supplement.

What qualifies my pet for enrollment?

Inclusion Criteria:

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

- Dogs strongly suspected of having urothelial carcinoma by the referring veterinarian.
    - All cases will be biopsy confirmed at OSUCVM following initial screening.
- Cancer must be primarily located within the bladder.
- Female dogs must weigh at least 6kg for inclusion.

- Males must weigh at least 10kg and be able to pass a catheter of minimum size through the urethra.
- Dogs must be at a normal weight (body condition score 4-7)
- Complete blood count and serum chemistry without clinically significant abnormalities, as determined by the veterinarian.

Exclusion Criteria:

- History of chronic gastrointestinal problems, skin problems
- Diagnosed with or treated for fecal parasites within the last three weeks.
- Treated with antibiotics within the last three weeks.
- Probiotic therapy or consuming a diet or treat containing probiotics within the last three weeks.
- Received H2 blockers or proton pump inhibitor within the last three weeks.
- Fed a raw diet in the last three weeks.
- Any history of chemotherapy or radiation, including for previous cancers.
- Additional requirements to participate in this study that will be determined by the veterinarian based on the screening appointment.

Diagnosis/Condition Being Studied: Bladder Cancer/Transitional Cell Carcinoma (TCC)

Intervention to Be Studied: Probiotic Supplement

Primary Outcome:
To determine if the addition of a probiotic can improve clinical outcomes when paired with a standard-of-care therapy (vinblastine/piroxicam) for canine bladder cancer - also known as urothelial carcinoma or transitional cell carcinoma (TCC). Our broader goal is to improve cancer care and outcomes in dogs with bladder cancer.

Primary Outcome Measure:
We will evaluate tumor response, clinical side effects, and quality of life over the 8 weeks of the clinical trial. Additionally, we will evaluate immune response and characterize the stool and urine microbiome and metabolome to understand the potential effects of the probiotic.

Primary Outcome Endpoint:
To determine if the addition of a probiotic can improve clinical outcomes when paired with a standard-of-care therapy (vinblastine/piroxicam) for canine bladder cancer - also known as urothelial carcinoma or transitional cell carcinoma (TCC). Our broader goal is to improve cancer care and outcomes in dogs with bladder cancer.

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

Pre-Screen HERE