A Prospective, Positive Controlled, Randomized, Parallel-armed and Masked Clinical Trial Designed to Evaluate the Efficacy and Safety of an Alternative Antibiotic Treatment Regimen for Lower Urinary Tract Infection in Dogs

Purpose of Study

The objective of this study is to evaluate the safety and effectiveness of an alternative antibiotic treatment protocol for uncomplicated lower urinary tract (bladder) infection in dogs.

Background

A bacterial infection in the lower urinary tract involves the bladder and urethra, which most often is resolved by administering antibiotics. Veterinarians are increasingly interested in dosing programs that reduce the time that animals and bacteria are exposed to antibiotics in order to minimize the risk of resistance development.

If the alternative antibiotic protocol is equally effective to a standard antibiotic administration, this could provide an option to the typical treatment of bladder infections. The alternative antibiotic administration schedule has the potential to limit the emergence of resistant organisms and to increase owner ease of treatment of bladder infections.

Major Inclusion criteria

To qualify for enrollment in this study, dogs must:

- Weigh 5-50kgs
- Have an uncomplicated bacterial lower urinary tract infection (LUTI). Dogs with persistent or recurrent LUTI based on clinical history are not candidates
- Not have chronic pyelonephritis, prostatitis, urinary tract neoplasia or calculi
- Have not been treated within 7 days with any short duration systemic antimicrobial or last 14 days with any long-duration systemic antimicrobial
- Have not been treated within the last 14 days with a systemic short-acting steroidal anti-inflammatory product or within the last 28 days with a systemic sustained-release steroidal anti-inflammatory product

Study Design

- Initial evaluation to determine if your dog is eligible for enrollment.
- If your dog fulfils all criteria for inclusion in the study he or she will be randomly assigned to a study group (both groups receive antibiotic treatment).
- Follow up evaluations will take place on days 10 and 21. A physical examination and LUTI scoring will be performed and urine samples will be collected for urinalysis as
well as bacterial culture and antimicrobial susceptibility testing.

**Client Compensation**

- The study will cover most costs related to the clinical trial including:
  - Initial Visit: Evaluation and LUTI scoring, CBC, chemistry, urinalysis, urine culture and sensitivity, and study medication
  - Two Follow Up Visits: Evaluations with LUTI scoring, urinalysis, and urine culture and sensitivity
- If your dog experiences treatment-related side effects, the study will pay for veterinary care and connected expenses.
- The study will not cover evaluations for other problems not related to the lower urinary tract, or if your pet becomes ineligible and further evaluation or treatment is needed.
- Owners must sign a consent form, be willing and able to comply with the established treatment procedure and schedule and complete the associated documentation, return for follow up visits, and return study documentation and unused medication.

**Contact Information**

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