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ILLINOIS
Veterinary Teaching Hospital
COLLEGE OF VETERINARY MEDICINE

Funded Clinical Trial:

A clinical trial of a novel probiotic therapy for canine chronic enteropathy
University of Illinois Small Animal Internal Medicine

Study Title:

A Double-Blinded, Randomized, Placebo-Controlled Clinical Trial to Assess the Therapeutic Efficacy of a Novel, Multi-Strain Probiotic in Dogs with Idiopathic Chronic Enteropathy

Background Information:

Idiopathic chronic enteropathies, including inflammatory bowel diseases, are common in dogs. Dietary modification is considered a first-line therapy for ICE but fails to induce satisfactory remission in approximately 50% of dogs. Antibiotics are also commonly prescribed, but recent studies have shown that they may exacerbate the problem by disrupting populations of “good” bacteria. Glucocorticoids (e.g. prednisone) are often effective but are associated with many adverse side effects. **Therapies that modify the GI microbiome are a promising alternative to existing treatments.** Probiotics contain living microorganisms that confer health benefits or treat disease in the host animal. We are evaluating a **new probiotic containing three bacteria that reduce intestinal inflammation and promote intestinal healing as a treatment for chronic enteropathies in dogs.**

Objectives:

The purpose of this clinical trial is to assess the efficacy of a novel probiotic in reducing clinical signs of gastrointestinal dysfunction in dogs with chronic enteropathy.

Eligibility:

Adult dogs (>1 years) with chronic (≥ 3 weeks) signs of gastrointestinal dysfunction are being recruited for this study. Candidate dogs must be free of enteric parasites on fecal examination, have no systemic diseases based on a CBC and serum chemistry panel, and have one or more of the following signs of gastrointestinal disease:

- Diarrhea,
- Vomiting
- Weight loss
- Changes in appetite

If you identify an eligible patient, please contact us to discuss the case.

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Study Design:

Eligible dogs will be examined at the U of I, and we will complete any additional diagnostics needed to screen for confounding diseases. Dogs that remain eligible will receive an abdominal ultrasound, gastroduodenoscopy, and histopathology.

Following enrollment, dogs will be randomly assigned to receive either the probiotic powder or a placebo. After 30 days, dogs in the placebo group will be switched into the probiotic group so that **all dogs enrolled in the trial will have the opportunity to receive the probiotic supplement.**

Participating clients will record observations of their dogs' clinical signs at home using a custom mobile phone-based application. Dogs will present for reexamination and collection of serum and feces periodically during the study. These recheck examinations can be performed at the U of I or at primary care clinics, depending on the preference of the client and referring veterinarian.

Benefits and Incentives:

1. **A thorough diagnostic evaluation** including an abdominal ultrasound, gastroduodenoscopy, histopathology, and consultations with veterinary specialists at **no cost** (approximate value **\$2000 value**).
2. **Access to a novel probiotic treatment that is not available elsewhere, at no cost.**
3. **Cash incentives up to \$300 for participating owners that complete the trial.**

Risks and Complications:

The procedures conducted in this investigation are either non-invasive (collection of blood and feces, ultrasound) or minimally invasive (endoscopy). The probiotic supplement has been demonstrated to be safe for administration to dogs and the bacterial species are approved by AAFCO. **While the risk of complications is minimal, the investigators will compensate clients for the cost of any medical care related to complications from this study.**

Contact Information:

If you have any questions about this study, do not hesitate to contact the investigators.

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Visit our clinical trial wiki page for more information:

<https://wiki.illinois.edu/wiki/x/wpOvKQ>