

Funded Study: Clinical Investigations in Feline Chronic Enteropathy

Study Title: Investigation of novel probiotic therapies and disease biomarkers in cats with chronic enteropathy

Purpose of Study/Background/Objectives: Feline chronic enteropathy (CE) is a gastrointestinal disease syndrome characterized by clinical signs of gastrointestinal dysfunction (weight loss, vomiting, diarrhea, changes in appetite) persisting for more than 3 weeks without an identifiable underlying cause. Chronic inflammatory enteropathy (CIE, previously called inflammatory bowel disease) is a common form of CE associated with imbalances in the gastrointestinal microbiome and intestinal mucosal inflammation. Currently, there are limited non-invasive diagnostic options for CE in cats and intestinal biopsies are often needed to identify CIE and differentiate it from other chronic intestinal diseases. Glucocorticoid drugs, the current mainstay of CIE treatment, can have substantial adverse effects. Therefore, there is a need to investigate new diagnostic and therapeutic strategies for CE in cats

This investigation has two objectives:

- 1) Validate novel biomarkers for the gut microbiome, intestinal permeability (“leaky gut”), and mucosal inflammation that can aid in the diagnosis of FCE and CE
- 2) Assess the therapeutic efficacy of a novel probiotic supplement for FCE and CIE

Inclusion Criteria:

- Adult (>1 year of age) cats with chronic (>2 weeks) clinical signs of gastrointestinal disease (weight loss, vomiting, diarrhea, changes in appetite, or some combination thereof).

Exclusion Criteria:

- Evidence of major systemic/metabolic and infectious disorders such as advanced chronic renal disease (>IRIS stage 2), uncontrolled hyperthyroidism, diabetes mellitus, feline leukemia virus (FeLV), feline immunodeficiency virus (FIV).
- Administration of glucocorticoids, antibiotics, probiotics or immunosuppressive agents within the two weeks prior to presentation. Cats receiving these medications are still eligible following discontinuation and a 2-week washout period.

Eligibility Diagnostics:

- The only diagnostics required prior to determining eligibility are those needed initially to screen for major systemic/metabolic and infectious diseases: serum chemistry panel, total T4, and FeLV/FIV test. These tests can be performed by the primary care veterinarian prior to referral, or at the U of I.
- Other diagnostics needed for enrollment will be performed at the U of I, including abdominal ultrasound, GI Health Panel (serum cobalamin, folate, fTLI, fPLI), endoscopy, and intestinal histopathology. The investigators will provide an incentive to offset the cost of these tests (approximate \$750 value, see below)

Treatment/Protocol:

- Cats must be evaluated by the Investigators at the U of I Small Animal Internal Medicine Service to confirm eligibility based on a diagnosis of CIE or another form of CE.
- Eligible cats will be enrolled in a double-blinded, randomized, placebo-controlled clinical trial of a novel probiotic supplement. During the trial they will be fed a therapeutic gastrointestinal diet (a hydrolyzed protein or novel protein diet, depending on what the cat prefers).
- The trial duration will be 8 weeks. Samples of blood and feces will be collected at baseline and after 4 weeks and 8 weeks during the trial.
- For clients who are not interested in participating in the clinical trial of the novel probiotic, cats can still donate samples for the biomarker investigation.

Owner Commitments:

- Provide the prescribed therapeutic diet and probiotic supplement for a total of 8 weeks
- Record information about your cat's health at home during the trial
- Bring your cat back to the U of I at two timepoints during the trial (4 weeks and 8 weeks) for collection of blood and fecal samples

Compensation:

- Costs for some of the advanced diagnostics (endoscopy, histopathology) of performed at U of I will be covered by the investigators for an approximately \$500-750 value.
- Clients that complete the 8 week clinical trial will receive a \$100 Amazon gift card.

Contact Information: For any questions related to the investigation, or to discuss any candidate cats, contact the principal investigator

Patrick Barko
Email: pcbarko@illinois.edu
Phone: 217-333-5300

