



## **Impact of Iron Deficiency on Short-term Response to Treatment in Cats with IBD**

### **Study Purpose:**

This study aims to compare if cats with inflammatory bowel disease (IBD) but without iron deficiency respond better to treatment for IBD than cats with iron deficiency.

Cats with gastrointestinal (GI) disease have low blood iron levels and low vitamin B12. Inflammation in the body caused by the GI disease can trap iron in cells, preventing its movement throughout the body. Cats with decreased appetites may also take in less iron through their diets and may have decreased absorption of dietary iron due to disease in the intestines. As iron is needed for the formation of red blood cells, this can result in decreased red blood cell formation. Low vitamin B12 levels decrease the body's ability to form red blood cells and cause structural changes within the intestines that decrease nutrient absorption, including iron. In people, low iron is associated with worse signs of GI disease, but this has not been studied in cats specifically with GI disease. If our study shows that cats with iron deficiency have a decreased response to standard-of-care treatment for GI disease, results would expand treatment options for cats affected by long-standing GI disease.

Prior to entry into this study, your cat must have a preliminary diagnosis of IBD, based on  $\geq 4$  weeks of GI signs (e.g. vomiting, diarrhea, weight loss), initial screening blood work, and abdominal ultrasound. All cats enrolled in the study must also have GI biopsies performed via endoscopy, to confirm the diagnosis of IBD and direct appropriate treatment.

### **Brief Study Description:**

Cats being considered to take part in this study, will have had blood drawn for initial screening blood work for measurement of red and white blood cell counts (CBC), chemistry panel (electrolytes and organ function), screening for vitamin B12 deficiency (MMA), iron deficiency (iron panel), disease-related inflammation (SAA), trypsin-like immunoreactivity (TLI) and thyroid (tT4) tests. Cats with eligible screening blood work and abdominal ultrasound, will be considered for this trial.

If your cat takes part in this study, he/she may need to have one additional blood draw initially to repeat any necessary test(s). Additionally, urine concentration will be measured in some cats to further evaluate kidney function if necessary. He/she will also have GI biopsies via endoscopy performed and will need to stay in the hospital the night prior to biopsies in preparation for the procedure. This is very similar to people preparing to have a colonoscopy procedure. Cats will go home the same day as the procedure. All procedures will be performed using standard protocol. He/she will need to return for rechecks two weeks, one month, and three months after initial enrollment for CBC, MMA, iron panel, and SAA. *Please note that the MMA and SAA tests repeated at the recheck visits are performed at study completion and results will not be immediately available.* We will also ask you to either bring a stool sample or take a picture of his/her stool at initial enrollment and all 3 rechecks.

## **Study Eligibility:**

### Inclusion criteria:

- Diagnosis of chronic gastrointestinal disease based on physical examination, chronic GI signs ( $\geq$  4 weeks vomiting, diarrhea, decreased appetite, weight loss), completion of screening blood work (CBC, chemistry panel), abdominal ultrasound, thyroid testing (tT4) and trypsin-like immunoreactivity (TLI) tests performed prior to study inclusion.
- Cats that have failed recommended conservative therapy such as food trials, when possible, and when biopsies are recommended for a definite diagnosis for individualized treatment recommendations.
- GI biopsies performed at the time of study inclusion.

### Exclusion criteria:

- Disease processes that can result in secondary GI signs (uncontrolled hyperthyroidism, exocrine pancreatic insufficiency, chronic kidney disease  $\geq$  IRIS stage 2) or other documented systemic disease (e.g. cardiac, respiratory)
- Cobalamin supplementation, hematopoietic stimulant administration, iron supplementation, steroid administration, or blood transfusion within the previous month. This is no longer an exclusion if it's been greater than 1 month.
- $<1$  year of age
- Patient unable to undergo general anesthesia for GI biopsies.

## **Client Compensation:**

For enrolled cats (those meeting eligibility), the study will cover the cost of the screening blood work as indicated above in addition to the urine specific gravity, if applicable, at the time of enrollment. The study will also cover the costs of the 3 follow-up appointments including the examination fee and associated blood work at each visit (CBC, MMA, iron panel and SAA). Additionally, the study covers the GI histopathology evaluation through Kansas State University, and owners are given a \$500 incentive toward costs of the upper and lower GI endoscopy and preparation.

No direct compensation is provided and the owner is responsible for additional testing, hospitalization, or additional treatments, as recommended by the attending clinician. Please note that MMA and SAA measurements are performed in bulk at study completion and results will not be available at the time of your cat's appointment(s).

## **Owner Responsibilities:**

Your cat will need to return to the Veterinary Health Center two weeks, one month, and three months after he/she had GI biopsies performed for blood draw (CBC, iron panel, MMA, SAA). You will need to provide us with either a stool sample or picture of your cat's stool at each of the 3 rechecks. We will also ask to you complete a survey about your cat's clinical signs, stool quality, as well as his/her current diet and other medications. ***Completion of the full course of the study provides your cat with three free recheck examinations and recheck lab work, as noted above.***

## **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](mailto:ClinicalTrials@vet.k-state.edu)