Veterinary Health Center
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Glucagon-like peptide 2 in cats with gastrointestinal disease – Inflammatory Bowel Disease Cats

Study Purpose: This study aims to evaluate if cats with inflammatory bowel disease (IBD) have different intestinal hormone (GLP-2) concentrations than healthy cats and to determine if GLP-2 concentrations affect short-term response to treatment of their IBD.

Inflammatory bowel disease (IBD) is the most common cause of long-standing vomiting and diarrhea in cats. Treatment options are limited, and treatment is typically life-long, with many cats having a lack of response to treatment. Glucagon-like peptide-2 (GLP-2) is a hormone produced by intestinal cells in response to food. This hormone is responsible for damage repair within the intestinal tract and decreases intestinal inflammation. In people with IBD, GLP-2 is not produced in normal amounts, and treatment with GLP-2 decreases severity of IBD. Cells that produce GLP-2 have been discovered in the intestinal tract of cats, and blood levels have been measured in healthy cats. However, blood levels have not been measured in cats with IBD. If our study shows that cats with IBD have different GLP-2 blood levels than healthy cats, results would help to improve monitoring and treatment options for cats with IBD.

Prior to entry into this study, your cat must have a preliminary diagnosis of IBD, based on ≥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 as part of the standard work-up, to confirm the diagnosis of IBD; biopsy results may help your cat's doctor make treatment recommendations for his/her specific disease.

Explanation: 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 and pancreatic function (MMA, PLI, TLI, cobalamin, folate), thyroid (tT4) tests, and baseline GLP-2 levels. Additionally, urine concentration will be measured in some cats to further evaluate kidney function if necessary. 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 will then be fed a small meal, using a canned commercial diet, and a second blood sample will be collected one hour later for measurement of GLP-2 concentrations in response to eating. 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. He/she will need to return for rechecks one month after initial enrollment for CBC, chemistry panel, and fasted/post-eating GLP-2 levels. *Please note that the MMA and GLP-2 tests are performed at study completion and results will not be immediately available.* We will also ask you to either bring a stool sample at initial enrollment and at the one-month recheck.

As a participant in this study, blood will be drawn using either a needle and syringe or butterfly catheter from a jugular or peripheral vein as deemed appropriate and the samples submitted for testing. Urine will be collected using a needle and syringe (cystocentesis). A nasogastric (NG) tube will be placed the night prior to GI biopsies and some cats may receive a small amount of sedation, if necessary, to facilitate placement. An x-ray will be taken to ensure the NG tube has been correctly placed. Cats will be monitored in ICU the night prior to the procedure and will receive a colonic prep liquid through the NG tube. This is very similar to people preparing to have a colonoscopy procedure; however, since cats won't readily drink the colonic prep, the NG tube is placed to assist with administering the solution. While under anesthesia and just prior to the procedure, cats will receive rectal enemas (warm water) repeated

until no fecal material is obtained. Biopsies will be taken of the stomach, upper small intestine, lower small intestine, and large intestine under general anesthesia. Cats will go home the same day as the procedure. All procedures will be performed using standard protocol.

Investigators:
Maria Jugan, DVM, MS, DACVIM (SAIM), Kansas State University, Clinical Sciences
Brandon Plattner, DVM, PhD, DACVP, Kansas State University, Diagnostic Medicine/Pathobiology

Eligibility:
Inclusion criteria:

- Diagnosis of chronic gastrointestinal disease based on physical examination, chronic GI signs (>/= 4 weeks vomiting, diarrhea, decreased appetite, weight loss), completion of screening blood work (CBC, chemistry panel, urine specific gravity, tT4), and abdominal ultrasound. In addition, vitamin B and pancreatic function tests will be performed at the time of study inclusion.
- 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 ≥ IRIS stage 2) or other documented systemic disease (e.g. cardiac, respiratory)
- Cobalamin supplementation or probiotic/steroid administration within the previous month.
- <1 year of age
- Patient unable to undergo general anesthesia for GI biopsies or diagnosis other than IBD on GI biopsies (e.g. cancer or fungal disease)

Risks: There are no expected long-term side-effects of blood draw. Some cats will have mild bleeding or bruising at the site of venipuncture and may need to wear a bandage for a few hours. Side-effects from cystocentesis are rare, but bleeding and need for transfusion and sudden collapse have been reported. There are no expected long-term complications of NG tube placement; placement confirmation by x-rays decreases risk of fluid administration into the lungs but pneumonia is a possible risk if vomiting were to occur during colonic prep liquid administration; this is considered a low risk. There are inherent risks of general anesthesia, including drug reaction, low blood pressure, and aspiration pneumonia, which can, in rare cases, lead to death. Your cat will be screened by its primary doctor and determined to be a good candidate for anesthesia. Anesthesia will be monitored under the supervision of a board-certified anesthesiologist to decrease these risks. Side-effects of endoscopy are rare but can include GI rupture, requiring emergency surgery, and increased GI gas accumulation and cramping the day following the procedure. We do expect stools to be loose/watery for 1-2 days due to enema preparation for the procedure.

Fees for Services: For enrolled cats (those meeting eligibility), the study will cover the cost of the screening blood work (CBC, chemistry profile) in addition to the urine specific gravity if applicable, GI panel (PLI, cobalamin, folate, TLI), and MMA at the time of enrollment. The study will also cover the costs of the one-month follow-up appointment, including the examination fee and associated blood work at each visit (CBC, chemistry profile, GLP-2). Additionally, the study covers the GI histopathology evaluation through Kansas State University and clonality testing (PARR) on the biopsies to help rule out cancer, and owners are given a $400 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 one month after he/she had GI biopsies performed for blood draw (CBC, chemistry panel, fasted and post-eating GLP-2). You will need to provide us with a stool sample at this recheck. 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 one free recheck examination 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