Blue Buffalo Clinical Trials Office

CVM-ClinicalTrials@osu.edu

Purpose and Brief Explanation of Study:

Uremic toxins are substances that build up in the body due to decreased removal by the kidney. They are increased in patients with CKD, correlate to severity of disease and contribute to progression of CKD. Porus One (Renaltec) is a new patented pure carbon product that traps protein byproducts in the gut so that they cannot be absorbed and converted into uremic toxins. The purpose of this study is to assess the efficacy of Porus One in cats with CKD.

What qualifies my pet for enrollment into this in this trial?

Cats with stable IRIS stage 2-4 CKD (serum creatinine \geq 1.6 - 8.0 mg/dL) that are willing to eat the product in wet food are potentially eligible to participate.

Exclusion criteria include other uncontrolled systemic illnesses, complications of CKD such as kidney infection or ureteral obstruction, severe anemia (PCV < 20%), and decompensated CKD requiring hospitalization and intravenous fluid therapy. Other concurrent therapies such as dietary management, potassium supplementation, anti-hypertensive medications and subcutaneous fluids are acceptable if they were initiated at least 14 days prior to enrollment and are given consistently throughout the study period. No antibiotics can have been administered within 8 weeks of enrollment and no prebiotics/probiotics or significant diet changes within one month of enrollment.

What does enrolling my pet in this clinical trial involve?

Your cat will need to be in the same fed state for every visit (either fasted or fed). At the time of screening, a complete history of diet and medications will be discussed. Your cat will receive a physical examination and comprehensive laboratory screening to confirm stage of CKD and exclude other newly diagnosed conditions (e.g. hyperthyroidism, hypertension). In addition, we ask that you bring fecal sample to evaluate the effect on the gut microbiome. This will also be the first time you fill out a quality-of-life survey.

After confirmation of enrollment, your cat will be randomized to start in one of the groups. This is a 16-week crossover study, meaning each cat will be in either the Porus One + standard of care group, or standard of care only group for 8 weeks and then cross over to the opposite group. Porus One will be administered sprinkled into wet food or cat snack (e.g. Churu) once a day for a total of 8 weeks. Administration should be greater than two hours from the time other medications are given.

Over the course of the 4-month study, your cat will be seen monthly for a physical exam and lab work. You will be asked to bring fecal samples to the visit and to fill out a quality-of-life survey at each visit. The study team will check in with you every two weeks by email or phone to address any questions or concerns. No changes in medication or diet should be made during the study without discussing first with the study team.

Client Compensation:

There is no cost to you for enrolling your cat in this study. You will receive complimentary physical examination for your cat and diagnostic testing.

Dr. Jessica Quimby Email: <u>Quimby.19@osu.edu</u>



If you believe your pet may be eligible for this study, please fill out a pre-screening questionnaire.

THE OHIO STATE UNIVERSITY VETERINARY MEDICAL CENTER