TriviumVet®

The REVERSE CKD Study

Study Summary

This is a multi-site, blinded, randomized, placebo-controlled clinical field study to evaluate the effectiveness of a novel drug intervention in the treatment of Chronic Kidney Disease (CKD) in client owned cats. The study will be conducted at multiple clinical sites that are experienced with CKD. The study will consist of a 14-day screening period, followed by a 9-month once-weekly dosing period, with five post-enrollment study visits.

Inclusion/Exclusion Criteria

A non-exhaustive list of the study inclusion and exclusion enrollment criteria are detailed below:

Inclusion Criteria

- Diagnosis of IRIS stage II or stage III CKD (creatinine ≥1.6 mg/dL and <5 mg/dL)
- Male or surgically spayed female cat
- Body weight ≥2.2 kg
- Age ≥5 years and <15 years at enrollment
- Constant environment and housing
- Stable diet for at least 28 days prior to screening
- If subject has undergone a general anesthetic within the last 6 months - clinical pathology results showing stable renal biomarkers

Exclusion Criteria

- Sexually intact female
- Cats unable to take and/or owners unable to administer oral medications
- UPC >0.4
- FIV or FeLV-positive cats
- Uncontrolled systemic hypertension or hyperthyroidism
- Malignant neoplasia of any body system in the last two years
- Diabetes mellitus
- Moderate or severe anemia (HCT <25%)
- Symptomatic cardiac disease
- Severe hypokalaemia or hyperkalemia
- Non-healed wounds or active infections
- Significant gastrointestinal disease
- Diagnosis of primary protein-losing nephropathy
- Cats enrolled in other studies currently receiving other investigational or experimental non-approved therapies

Study Assessments

A summary of the study assessments to be conducted over the course of the REVERSE study is provided below.

Procedure	Screening 1	Screening 2	Enrolment day	Day 0	Day 30 ± 3	Day 90 ± 10	Day 180 ± 10	Day 270 ± 10
Medical history	🐾	🐾	🐾	Owner collects study drug from investigator site	🐾	🐾	🐾	🐾
Dietary History	🐾	🐾	🐾		🐾	🐾	🐾	🐾
Physical examination	🐾	🐾	🐾		🐾	🐾	🐾	🐾
Abdominal rads & ultrasound	🐾							
Systolic blood pressure	🐾	🐾	🐾		🐾	🐾	🐾	🐾
Clinical Pathology Sampling (urine & blood, inc. FeLV and FIV screen)	🐾	🐾	🐾		🐾	🐾	🐾	🐾

Study participation incentives

- Opportunity for your client to access a novel treatment.
- Client access to veterinary care for the duration of the study.

How to refer

- Visit ckdincats.com
- Select the investigation site most local to you
- Select the veterinarian form
- Complete this form with details of the client/patient
- The investigator site will contact the owner as screening slots become available should the patient meet the inclusion criteria for the study. Study enrolment may be staggered at each investigation site.