ART
Azodyl Renal failure Trial

Study Design:

Multi-center, double-blinded prospective study. One hundred cats will be randomly assigned to receive either Azodyl (1 to 3 capsules daily) or placebo. The dosages chosen for the Azodyl are based on manufacturer recommendations.

Inclusion criteria:

Cats of any age and sex will be eligible for study entry. Cats must have previously documented chronic renal failure which is not rapidly progressive and of at least 2 months duration. "Rapidly progressive" is defined as significantly worsening indices of renal function over the previous 2-6 months or development of uremia in the previous 2-6 months. Cats must have objective evidence of non-infectious chronic renal failure, as determined by elevated blood urea nitrogen (BUN) and creatinine (Creat) with isosthenuria (USG <1.030). Owners will complete a monthly survey that will record appetite, activity, psychological status, thirst, degree of interaction with owner, and side effects of medication prior to routine sampling. Cats with controlled hypertension are eligible.

Exclusion criteria:

Cats with chronic renal failure diagnosed less than 2 months.

Cats with co-morbidities that are likely to impact clinical status (e.g. diabetes, hyperthyroidism, heart disease).

Cats with uncontrolled hypertension or untreated hypertension.

Cats with acute renal failure or renal failure of infectious or neoplastic causes.

Definition of Chronic Renal Failure:

Elevation in BUN and Creatinine with isosthenuria of at least 2 months duration. Cats should generally demonstrate weight loss at time of initial diagnosis, and have polyuria and polydipsia as a presenting clinical finding. Urine culture, if performed, should be negative. Non-regenerative anemia may be present. Physical exam findings may include abnormally palpable kidneys.

Blinding procedures:

In order to avoid bias, primary care clinicians and owners will not be provided details of the biochemical tests during the study UNLESS clinically mandated by the primary care clinician. If results are required for acute management decisions, the investigators should be contacted.

Dosing protocol:

Cats <5lbs: 1 capsule daily (AM) **sprinkled** onto food

Cats 5-10lbs: 1 capsule twice daily (AM and PM) **sprinkled** onto food

Cats >10lbs: 2 capsules AM and 1 capsule PM. **sprinkled** onto food

Capsules must be sprinkled onto food.

To ensure consistent dosing, a small portion of canned food will be provided with capsule contents mixed through the food prior to feeding the remainder of the meal.

Concurrent Medications and Therapies:

Cats enrolled in the study may receive additional medications and therapies for their renal failure throughout the course of the trial, provided these therapies have been administered routinely for at least 2 months prior to enrollment in the clinical trial. The medications should be continued for the duration of the trial at the same doses and dosing frequencies.

Medications and therapies can include (but are not limited to) calcitriol, dietary protein restriction (i.e. renal failure diets), subcutaneous fluid administration, erythropoietin

administration, histamine receptor antagonists (H2 blockers), potassium supplementation, phosphate binding agents, amlodipine or angiotensin-converting enzyme inhibitors, alkalinizing agents.

If changes in therapy are required during the trial for acute management of CRF complications or progression, the primary care clinician should contact the study coordinators.

Study schedule:

1) **Study entry** Once a cat is enrolled, laboratory tests (hemoglobin, hematocrit, blood urea nitrogen, plasma creatinine and serum albumin) will be performed for baseline time point. Cats will be weighed and a body condition score will be estimated. The cat will be randomly assigned to receive Azodyl or placebo.
2) **One month baseline recheck:** Cats will have a second baseline evaluation after one month to ensure stability of CRF. Owners will complete survey prior to each visit (initial and 2nd baseline visit). Cats will be weighed and a body condition score will be estimated. Blood work (hemoglobin, hematocrit, blood urea nitrogen, plasma creatinine and serum albumin) will be performed to evaluate for stability of CRF. Therapy with assigned medication will commence following this visit.
3) **Two month recheck:** Identical to one-month recheck. Owners will complete questionnaire prior to visit.
4) **Three month recheck:** Identical to two-month recheck.. At this time, participants will be able to request identification of treatment.

Primary end-point: Completion of 3-month study.

Cats with progressive clinical signs will not be withdrawn from the study unless owners request removal.

Procedural Reimbursement:

Study Drugs (Azodyl or placebo)	**supplied by principal investigators**
Biochemical testing	**supplied and covered by investigators**
Clinic visits	**Each practice participating in the trial will receive a free VSPN handbook for the practice courtesy of VIN.**