The Effect of Transdermal Mirtazapine on Quality of Life in Cats

Blue Buffalo Clinical Trials Office

CVM-ClinicalTrials@osu.edu

Purpose and Brief Explanation of Study:

Clinical signs of nausea, vomiting and dysrexia (abnormal appetite behaviors) are common in feline patients with chronic kidney disease (CKD). Weight loss and loss of lean body mass in these patients is likely attributable to changes in appetite as well as processes such as cachexia (weight loss due to an underlying illness) and sarcopenia (loss of muscle mass and function associated with aging). Poor appetite is perceived as an important aspect of quality of life and can cause significant emotional distress to caregivers. A better understanding of the effect of management of inappetence in CKD on quality of life will improve our ability to help feline patients with CKD. Therefore, the purpose of this study is to assess the effect of appetite stimulation on quality of life in cats with CKD.

What qualifies my pet for enrollment into this trial?

- Cats with stable, confirmed IRIS stage 2-3 CKD (serum creatinine ≥ 1.6 - 5.0) measured on two consecutive occasions in conjunction with a USG < 1.035) that have not received an appetite stimulant in the last two weeks are potentially eligible to participate.
- Other concurrent therapies such as therapies for CKD and subcutaneous fluids are acceptable if they are given consistently throughout the study period and have been started at least 2 weeks prior to enrollment. Major dietary changes must have been started at least 2 weeks prior to enrollment.

Exclusion criteria include the presence of other uncontrolled systemic illnesses, including those with complications of CKD such as urinary/kidney infection or ureteral obstruction, moderate to severe anemia (PCV < 25%) and initiation of other appetite stimulants.

What does enrolling my pet in this clinical trial involve?

At the time of screening, your cat will receive a physical examination and comprehensive laboratory screening to confirm stage of CKD and exclude other newly diagnosed conditions. They will then be randomized to receive either mirtazapine transdermal ointment or placebo. Both are an ointment that will be administered transdermally to the inner surface of the ear flap once daily. Cats will be randomized into one of two groups (mirtazapine or placebo) and then switch to the other group after two weeks. We will follow up via phone one week following enrollment to address any questions or concerns. You will bring your cat back for two recheck visits (Week 2 and Week 4) for a physical exam, blood and urine collection and blood pressure measurement. From the time of initial screening to the completion of the study, you will be asked to complete the online Vetmetrica Quality of Life survey* - a validated instrument to assess quality of life in cats - on a weekly basis, as well as a daily log of appetite.

Client Compensation:

There is no cost to you for enrolling your cat in this study. The exams and diagnostics performed at enrollment, Week 2 and 4, and the cost of the mirtazapine transdermal ointment medication used, are covered by the study alone. In the unlikely situation that an adverse event that requires treatment occurs as a result of taking part in this study, the cost of treatment will be covered by the study.

Dr. Jessica Quimby
Email: Quimby.19@osu.edu

Dr. Lina Lim
Email: Lim.1136@osu.edu

Pre-Screen HERE

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