Veterinary Health Center
University of Missouri

Osteoarthritis Medication Clinical Trial

Title: Evaluation of a novel disease-modifying osteoarthritis drug (DMOAD) and its effect on the development and progression of osteoarthritis in dogs following cranial cruciate ligament (CCL) rupture and tibial plateau leveling osteotomy (TPLO) surgery

Investigators:
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Study Description:
Disease-modifying osteoarthritis drugs (DMOADs) are expected to affect the joint structure (slow osteoarthritic changes from occurring) as well as have effects on clinical signs, while maintaining good long-term safety. A novel DMOAD that shows promising results experimentally will be evaluated for its effect on the development and progression of osteoarthritis in dogs following surgical repair of a ruptured cruciate corrected by Tibial Plateau Leveling Osteotomy (TPLO) surgery.

Inclusion Criteria:

- Dog is at least 2 years of age or has reached skeletal maturity as determined by Investigator
- Dog weighs ≥15 kg and ≤56 kg
- Dog had onset of lameness associated with unilateral Cranial Cruciate Ligament (CCL) rupture within the last 9 months
- Dog had Tibial Plateau Leveling Osteotomy (TPLO) at least 2 months, but no more than 4 months prior to enrollment
- If female, dog is non-pregnant and non-lactating; Owners should not be planning to breed the dog
- Owners that can commit to the study for a period of 1 year

Exclusion Criteria:

- Dogs that are regularly taking a product for pain control (e.g., NSAIDs, opiates, tramadol, etc.)
- Dogs that are regularly taking a product for joint health or prevention of osteoarthritis

health (e.g., chondroitin, etc)
- Dogs that have been changed to a prescription joint health diet within the last 30 days
- Dogs with radiographic score greater than 20 at enrolment
- Dog is pregnant or lactating
- Dogs that have any non-stabilized disease or conditions that, in the opinion of the Investigator, could compromise or confound the measurement of outcomes or overall patient safety
- Dog is owned by study veterinarians or study personnel
- Dogs currently enrolled in another clinical trial

Each dog that qualifies for the study will receive a baseline evaluation that includes the following: orthopedic examination by a board-certified veterinary surgeon, radiographs (x-rays) of the affected joint, and a complete biomechanical and musculoskeletal gait evaluation, and CT scan of the operated stifle. In addition, approximately 1 tablespoon of blood will be collected for lab work (CBC and chemistry profile) along with urine for urinalysis. Dogs will be randomly assigned to receive the DMOAD or placebo, to be administered once daily for 360 days. Recheck examinations will be required on Days 30, 90, 180 and 270 of the study for repeat physical exam, blood and urine collection, biomechanical and musculoskeletal gait evaluation, radiographs of the operated stifle, and overall assessment of their dog's condition. A repeat CT scan will be performed on Days 180 (6 months) and 360 (12 months). Additionally, owners will be contacted by telephone on Days 60, 135, 225, and 315 for an update on their dog and to complete a questionnaire.

****All procedures described above will be paid for by the study. In addition, owners will receive $500.00 paid in increments throughout the study.**

Duration of Study:
The study is currently OPEN.

Potential Benefits to Veterinary Medicine:
Currently, therapeutics aimed at preventing progression of osteoarthritis are limited. Data may show that treatment with this drug may provide disease modifying protective effects against osteoarthritis.