CSU Veterinary Health System

Place Patient Identification Sticker Here

Appointment Desk: (970) 297-5000
http://csu-cvmbs.colostate.edu/vth/

Clinical Trials: Owner Informed Consent

Evaluation of two joint supplementation formulas for the treatment of naturally-occurring canine osteoarthritis

Overview of the Study

The purpose of this study is to evaluate the efficacy of an oral supplement on lameness and function in dogs affected by naturally occurring osteoarthritis (OA). Your dog will receive a supplement to his or her current diet that will be one of two different formulas (containing different amounts of special ingredients that are designed to reduce the effects of pain/discomfort associated with osteoarthritis based on a commercially available supplement: Platinum CJ - https://www.platinumperformance.com/platinum-performance-canine-cj/CPCJG.html#product-tabs) during the two phases of the study. The supplement has to be given daily for the duration of the study. Your dog will be receiving serial evaluations (7 visits) over approximately 5 months and be randomly assigned to the two supplements for the different phases. All supplements/evaluations/treatments will be provided free of charge. If all study visits, forms and other requirements (such as filling out the questionnaires as well as required tax documents) are fulfilled, you will receive an incentive of $500 after completion of the study. Your dog will need to be returned to the CSU-VTH for a total of 7 visits for data collection and to receive either supplement.

We are utilizing objective gait analysis (i.e. a non-invasive procedure) to provide an objective outcome measure of improvement in weight bearing/lameness. We are recruiting dogs that have a consistent lameness due to osteoarthritis. The study involves your dog undergoing additional diagnostic tests including x-rays, blood draws and gait analysis. Prior medications and treatments (except oral supplements) are to be continued consistently during the duration of the study.

Expected Duration of Participation: 20 weeks (see detailed outline below)

Description of Procedures and Possible Discomforts and Risks

- Gait analysis requires your dog to walk on a flat surface over a pressure-sensing mat embedded in the floor. No adverse events are expected from this procedure.
- Blood will be obtained from the neck or limbs. Minor side effects may include bruising or clotting at the site of the blood draw.
- Sedation may be necessary for x-rays. While every attempt is made to minimize the risks associated with this procedure, possible side effects may include temporary drowsiness, lethargy, kidney or other organ damage, and death.
- Clipping for catheter placement of blood draw may cause minor, self-limiting skin irritation. No other side effects are expected.
- Temporary soft stool, pruritic skin, or upset stomach due to change in diet.

Enrollment Benefits

- The following benefits are provided to your pet for enrolling in this research:
    i. Your pet will receive free X-rays of affected joint.
    ii. Your pet will receive a free CBC at day 0
    iii. Recheck fees and all additional procedures associated with the study (sedation, x-rays) are covered by the study.
    iv. You will receive an incentive of $500 if all study requirements are fulfilled after the final visit. Specially, these requirements include:
        - Completion of all study visits at the scheduled time points
        - Completion of all required forms/questionnaires/logs by the same owner
        - Completion of required tax documents
        - Adherence to the feeding protocol
        - Response to email requests/phone calls within 2 business days
        - Contacting us immediately if your animal is experiencing worsening of symptoms so that we may schedule an evaluation and potentially offer additional pain management strategies

Extent of Confidentiality of Records

- Your pet's medical records will be kept confidential and any resulting publication will only identify your pet as a number rather than individual names.

Compensation or Therapy for Injuries

- In the unlikely event that your pet sustains an injury directly related to the study, treatment for the injury will be provided to you by the study, free of charge.

Contact Person for the Study

- The contact person for this study is Dr. Felix Duerr (Principal Investigator and veterinarian). His contact information is listed at the bottom of this form.

Voluntary Participation and Right to Withdraw

- Please be advised that by consenting to participate in this study you agree to allow the research coordinators to perform all of the procedures as outlined. As a volunteer you have the right to withdraw your pet from the study at any time, for any reason. Please note that if you elect to withdraw your dog from the study, you will NOT receive the study incentive.

Termination of Participation by the Principal Investigator

- The Principal Investigator and research coordinators reserve the right to exclude your pet from participation in the study at any time, for any reason.

Study contact person: Dr. Felix Duerr, Primary Investigator; 970-297-5000; felix.duerr@colostate.edu

I understand that the veterinarians at this institution are engaged in research for the improvement of animal health, patient care, education, clinical investigation, and scientific innovation.

The details of the Evaluation of the effect of nutritional supplement on naturally occurring osteoarthritis-associated pain in dogs Clinical Trial have been explained to me by:

Dr. _____ on _____.

Please initial the following lines to note your understanding of the parts of this study:

☐ I have been able to ask the researcher questions and state any concerns
☐ The researcher has responded to my questions and concerns

☐ I believe I understand the research study and the risks that are involved.
☐ I give my permission to publish data and photos obtained from this study for the benefit of the scientific community. I understand that my pet will not be identified individually.
☐ I may withdraw my pet from this study at any time without penalty (however, the study incentive will not be paid).
☐ The veterinarian in charge may withdraw my pet from this study if he/she determines that my pet is adversely affected.
☐ I have been given the opportunity to have ample time to make the decision to enroll my pet in this particular study and feel comfortable moving forward with enrollment in this study based on the information provided.
☐ I understand that any prescribed recheck examinations/treatments recommended by my veterinary team that are unrelated to the study will not be covered by the study.
☐ I understand that the funding for this study is provided by ZOETIS/Platinum Performance (the provider of the supplement).
☐ Other (non-study) treatments have been discussed with me, and I understand the benefits of those treatments.
☐ I realize that it is possible my pet will not get better from being a part of this study.
☐ I agree to these specific study criteria (A-H):

A. I will return my dog for visits 1-7.
B. My pet must have confirmed, consistent OA based on radiographs
C. I will fast my dog before visit 1 if sedation is required.
D. I expect that each visit may take up to 4 hours (drop-off and late pick-up can be arranged)
E. I allow my dog to undergo additional diagnostics (sedation, x-ray, blood draw) as outlined.
F. I allow my dog to undergo objective gait analysis (walking over a pressure platform).
G. I will allow my dog to wear an activity monitor that monitors my dog's daily activity.
H. I will leave the provided devices/collar on my dog at all times (the devices are waterproof for up to 20 minutes of immersion). If the device is removed for any reason, I will indicate this on the daily log.
I. I will follow the feeding instructions, providing the daily supplement and fill out the dietary log.
J. I will not change my pet's medication regime without discussing the changes with the investigators

☐ I understand that information and samples collected during this study are the property of the investigator and may be stored for future use.

☐ I understand that someone may contact me after my pet has finished this study to collect follow-up information. This may occur several months to years following the end of the trial.

As a result of discussion with Dr. _____, and after reading the above, I voluntarily consent to participate in this project and will follow the instructions of the veterinarians-in-charge as it pertains to therapy and follow-up tests.

Signed _____ Date _____
Owner or authorized agent of the owner

Witnessed By: _____ Date _____

For questions about this study, please contact: Orthopedic Medicine and Mobility Clinical Trials at (970) 497-3706 or OrthoResearch@colostate.edu

Study Timeline

CBPI=Canine Brief Pain Inventory (a pain questionnaire to be filled out)
CSOM=Client Specific Outcome Measures (a pain questionnaire to be filled out)
OGA=Objective Gait Analysis
SOS=Subjective Orthopedic Scoring (=veterinary exam)
Accelerometer = Activity Tracker
CBC/CHEM=bloodwork

Week -1: Evaluation Visit
- Accelerometer placement
- CBC/Chem profile
- CBPI & CSOM; OGA

Week -1 to 0: NO treatment

Week 0: Baseline Visit 1
- Blood collection for biomarkers
- OGA; CBPI & CSOM
- SOS

Week 0 to 4: Treatment Phase 1

Week 4: Outcome Visit 1
- Blood collection for biomarkers
- OGA; CBPI & CSOM
- SOS

Week 4 to 8: Treatment Phase 2

Week 8: Outcome Visit 2
- Blood collection for biomarkers
- OGA; CBPI & CSOM
- SOS

Week 8 to 11: Twenty-one Day Washout Period

Week 11: Baseline Visit 2
- Blood collection for biomarkers
- OGA; CBPI & CSOM
- SOS

Week 11 to 15: Treatment Phase 3

Week 15: Outcome Visit 3
- Blood collection for biomarkers

- OGA; CBPI & CSOM
- SOS

<u>Week 15 to 19</u>: Treatment Phase 4

<u>Week 19</u>: Outcome Visit 4

- Blood collection for biomarkers
- OGA; CBPI & CSOM
- SOS