

Cannabis-based product for canine osteoarthritis



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Place Patient Identification Sticker Here

Clinical Trials: Owner Informed Consent

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Brief study overview

Your dog has been diagnosed with osteoarthritis (OA) and while many treatments are available, the ideal treatment of OA is still unclear. We are investigating the use of cannabidiol (CBD) product administered twice daily for the treatment of OA. While previous studies have suggested that CBD has pain-relieving and anti-inflammatory properties, studies that evaluate the efficacy of CBD for canine osteoarthritis using objective measures of lameness have not been conducted.

We will use several outcome measures (gait analysis, exams and questionnaires) over a time-period of 3 months to evaluate the efficacy of the treatment. All costs associated with the study will be covered upon enrollment, including recheck exams, bloodwork, and radiographs of the joint(s). And your dog will receive the CBD product free of charge for the duration of the study. Monthly visits are required when enrolling in this study.

If you have any questions before enrolling or during the study please contact Dr. Stephanie McGrath (stephanie.mcgrath@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 detailed procedures of the **'Evaluation of cannabidiol as a treatment option for canine osteoarthritis'** clinical trial have been explained to me by:

Dr. _____ on _____.

Please check the following boxes to confirm your understanding of the components of this particular study:

- My pet must have a confirmed diagnosis of osteoarthritis to be eligible to participate in this study.
- The purpose of this study is to evaluate the clinical value (i.e. improvement in lameness and activity level) of cannabidiol as a treatment for osteoarthritis in dogs.
- My pet will be treated by a group of veterinarians specializing in clinical research. My pet will be treated and evaluated with the following procedures over a 4-month time period (a visit once a month is required during the study period):
 - Radiographs
 - Gait analysis (approximately 4-5 times, depending on the need to adjust medications for your individual dog this may be more frequently)
 - Monthly physical exams, including lameness exam, joint range of motion exams, and limb circumference measurements to track treatment effects

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- A previous safety study using this product found mild side effects, including diarrhea, vomiting, and slight changes in liver enzymes. However, since this product has not been used in any clinical trials, the efficacy is currently unknown. The treatment may be beneficial for your dog and is of low risk. *I understand the risks involved with CBD and realize that it is possible my pet will not benefit from this treatment.*
- All methods used have been carefully tested individually to minimize potential side effects. However, I realize it is possible my pet will experience unexpected side-effects which could be mild, moderate or severe. My pet will be observed closely for side effects and appropriate action will be taken. If the lameness worsens after the CBD administration, the standard treatment (pain medications is usually sufficient for resolving the lameness) will be altered, which may mean my pet will be withdrawn from the study.
- The potential side effects of CBD administration (lack of efficacy, pain, allergic reaction, vomiting, diarrhea, inappetance, ataxia, worsening of lameness) have been explained to me and I understand the risks and potential benefits. Please contact the emergency service if severe side effects are observed.
- This is a cannabis product comprised primarily of cannabidiol (CBD), a non-psychoactive cannabinoid. There are negligible amounts of the psychoactive component, THC. Therefore, the drug will not cause the “high” or toxic effects that marijuana causes. I understand that this product is intended for animal use only.
- Alternate (non-study) treatment protocols have been discussed and I understand the relative benefits of those treatments.
- I understand that I will be receiving the treatment, radiographs, gait analysis, and monthly physical exams free of charge.
- I understand that I am financially responsible for any treatment for my pet's condition not specifically related to this study.
- I understand that I must return to CSU for the prescribed recheck examinations following entry into the study. I realize that the costs for treatment once the study has ended will not be covered.
- 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.
- The veterinarian in charge may withdraw my pet from this study if he/she determines that my pet is adversely affected.
- I may discuss this procedure with my own veterinarian and ask his/her advice.
- I understand that someone may contact me after my pet has finished this clinical trial to collect follow-up treatment and outcome information. This may occur several months to years following completion of the trial.
- 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 the funding for this study is provided by the company producing the CBD product (Applied Basic Science Corporation).
- I understand that one or more of the investigators in this study may have a conflict of interest. For this particular study, the principal investigator is being funded by the pharmaceutical company, Applied Basic Science Corporation.

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I understand that my dog will wear an activity monitor that measures daily activity. This device is NOT waterproof and should be removed prior to my dog swimming.

I agree to these specific study criteria (A-E):

- A. I will not change any aspect of my dog's osteoarthritis treatments without informing the CSU team involved with this study within a reasonable time period
- B. I will bring my dog for regularly scheduled appointments with the CSU rehabilitation department
- C. I am allowing the research team to access my dog's activity and location data remotely
- E. I agree to fill out questionnaires and daily activity logs throughout the study

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 procedures.

Signed _____
Owner or authorized agent of the owner

Date _____

Witnessed By: _____

Date _____