



Appointment Desk: (970) 297-5000

<http://csu-cvmb.colostate.edu/vth/>

Clinical Trials: Owner Informed Consent

Place Patient Identification Sticker Here

## Evaluation of the effects of an oral supplement on muscle mass recovery after tibial plateau leveling osteotomy (TPLO) in dogs

*Please read through the following important information about this study and how your pet may be involved. If you have any questions, please don't hesitate to ask for clarification!*

### Overview of the study

The purpose of this study is to evaluate whether an oral supplement can accelerate muscle mass recovery after TPLO. Your dog will receive a supplement to his or her current diet that may be a placebo or treatment (supplement that contains special proteins that are designed to accelerate muscle mass recovery) provided in the form of kibbles. The supplement has to be given daily for the first 8 weeks after the surgery. The secondary purpose of the study is to compare inflammatory markers (blood levels) after this procedure. We are utilizing ultrasound (i.e. a non-invasive procedure) to evaluate changes in muscle mass (i.e. muscle mass recovery) in dogs after surgery. Objective gait analysis will be utilized to provide an objective outcome measure of improvement in weight bearing/lameness. We are recruiting dogs that are undergoing a TPLO-procedure and offering a variety of incentives (outlined below) in exchange for participation in this study. The study involves your dog undergoing additional diagnostic tests including blood draws, gait analysis and ultrasound measurements of the limb before surgery and 2, 4 and 6 weeks after surgery. The procedure (TPLO) itself will not be affected by participation in this study.

### Expected Duration of Participation

- This study involves a commitment to multiple visits. The visits are as follows:
  - **Day 0** (i.e. the time of your dog's surgery)
    - i. Additional tests performed:
      - Ultrasound of the limb
      - Blood draw (5.5 ml)
      - Gait analysis
  - **Weeks 2 (suture removal) and 4 after surgery**
    - i. Additional tests performed:
      - Ultrasound of the limb (this will require clipping the area where the ultrasound is performed in the middle of the thigh again)
        - a. Sedation may be required for this procedure
      - Blood draw (5.5 ml)
      - Gait analysis
  - **Week 6 after surgery** – this visit is the first time point where recheck X-rays will be performed to evaluate bone healing (free of charge).
    - i. Additional tests performed:
      - X-rays of the limb
      - Ultrasound of the limb (this will require clipping the area where the ultrasound is performed in the middle of the thigh again)
        - a. Sedation may be required for these procedures

# TPLO Muscle Recovery Study

- Blood draw (5.5 ml)
- Gait analysis
- **Week 8 after surgery** – this visit is the second time point where recheck X-rays will be performed to evaluate bone healing (free of charge) – NOTE: Most dogs are sufficiently healed by this time point, however, if healing is delayed you may be asked to return for a later recheck (which is NOT covered by the study) since the study period ends at 8 weeks.
  - i. Additional tests performed:
    - X-rays of the limb
      - a. Sedation may be required for these procedures
    - Gait analysis

## Description of Procedures and Possible Discomforts and Risks

- Diagnostic ultrasound will be used to measure muscle size. No adverse events are expected from this procedure, but sedation may be required.
- Gait analysis requires your dog to walking 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 ultrasound and blood draw. 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 may cause minor, self-limiting skin irritation. No other side effects are expected.

## Enrollment Benefits

- The following benefits are provided to your pet for enrolling in this research:
  - i. Your pet will receive free X-rays at the 6 and 8 week recheck.
  - ii. Your pet will receive a free CBC at 0, 2, 4 and 6 weeks.
  - iii. Recheck fees at 2, 4, 6 and 8 week time points and all additional procedures associated with the study (sedation, ultrasound) are covered by the study.
  - iv. Participation in the study provides you with an \$850 credit. Please note that this credit will only be given if:
    - Your dog is returned for ALL recheck visits
    - You follow the feeding instructions and return the dietary compliance form as well as all empty (or partially empty) bags

## 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.

## 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.

# TPLO Muscle Recovery Study

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

**Please check the following boxes to confirm your understanding of the components of this particular 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.
- The veterinarian in charge may withdraw my pet from this study if he/she determines that my pet is adversely affected.
- I may discuss the diagnostic procedures (ultrasound, blood draw) with my own veterinarian and ask his/her advice.
- 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 Nestec (the provider of the nutritional supplement).
- I agree to these specific study criteria (A-H):
  - A. I will return my dog for visits at 2, 4, 6 and 8 weeks after surgery.
  - B. I will fast my dog before each visit since sedation may be required.
  - C. I expect that each visit may take up to 8 hours (drop-off and late pick-up can be arranged)
  - D. I allow my dog to undergo additional diagnostics (ultrasound, blood draw) as outlined.
  - E. I allow my dog to undergo objective gait analysis (walking over a pressure platform).
  - F. I will allow my dog to wear an activity monitor that monitors my dog's daily activity.
  - G. 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.
  - H. I will follow the feeding instructions and fill out the dietary compliance form.

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 the effects of an oral supplement on muscle mass recovery after tibial plateau leveling osteotomy \(TPLO\) in dogs](#) clinical trial have been explained to me by:

Dr. \_\_\_\_\_ on \_\_\_\_\_.

As a result of discussion 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 \_\_\_\_\_ Date \_\_\_\_\_  
Owner or authorized agent of the owner

Witnessed By: \_\_\_\_\_ Date \_\_\_\_\_

Please contact us if you have any questions or concerns. Dr. Felix Duerr (Principal Investigator) [Felix.duerr@colostate.edu](mailto:Felix.duerr@colostate.edu)

**Study Calendar**

Study Week	Additional procedures for study purposes
Week 0 (time of surgery)	<ul style="list-style-type: none"> <li>• Gait analysis</li> <li>• Activity monitoring</li> <li>• Orthopedic exam</li> <li>• Blood Draw</li> <li>• Ultrasound</li> <li>• Initiation of feeding supplement/placebo</li> </ul>
Week 2 (Day 14)	<ul style="list-style-type: none"> <li>• Gait analysis</li> <li>• Activity monitoring</li> <li>• Orthopedic exam</li> <li>• Blood Draw</li> <li>• Ultrasound</li> <li>• Sedation</li> </ul>
Week 4 (Day 28)	<ul style="list-style-type: none"> <li>• Gait analysis</li> <li>• Activity monitoring</li> <li>• Orthopedic exam</li> <li>• Blood Draw</li> <li>• Ultrasound</li> <li>• Sedation</li> </ul>
Week 6 (Day 42)	<ul style="list-style-type: none"> <li>• Gait analysis</li> <li>• Activity monitoring</li> <li>• Orthopedic exam</li> <li>• Blood Draw</li> <li>• Ultrasound</li> <li>• X-rays</li> <li>• Sedation</li> </ul>
Week 8 (Day 56)	<ul style="list-style-type: none"> <li>• Gait analysis</li> <li>• Activity monitoring</li> <li>• Orthopedic exam</li> <li>• X-rays</li> <li>• Sedation</li> </ul>