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Veterinary Teaching Hospital
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Clinical Research Project
Client Consent Form

Study Title: Effect of treatment with spironolactone in dogs with pulmonary hypertension and myxomatous mitral valve disease

Principal Investigator: Michele Borgarelli
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One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is entirely voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate. CVCA Cardiac Care for Pets - Leesburg is a partner in this multi-center study.

Study Purpose:
Pulmonary hypertension (PH) is a common complication of mitral valve disease (MVD) in dogs and it increases almost twice their risk of death. Spironolactone is a diuretic drug that could have some beneficial effects at the level of the pulmonary vessels. We hypothesize that treatment with spironolactone, in addition to conventional therapy for congestive heart failure (CHF), will improve PH secondary to MVD.

Study Design/Procedures:
Our objective is to evaluate the effect of treatment with spironolactone on pulmonary pressure at 1 week and 1 month in dogs with moderate to severe PH secondary to MVD.
An initial visit comprehensive of heart ultrasound, chest X-rays, and blood sampling will be performed, and your dog will then be randomly assigned to receive either spironolactone or a placebo (a pill that looks exactly like the drug, but that does not contain any active principle) every day for a month as directed. Both you and the clinician will be unaware whether your dog is receiving spironolactone or the placebo. The ultrasound and blood sample will be repeated after 1 week and 1 month from your initial visit. The chest x-rays will also be repeated at the 1 month visit. Your dog will continue to receive all the other drugs that was receiving before the enrollment.

Risks and Benefits:
All the procedures involved in this study are minimally invasive and they are usually not associated with significant risk for the patient. Given the severe heart condition of your dog, any excessive stress or manipulation could lead to a reoccurrence of congestive heart failure, which is life-threatening. All efforts will be made in order to minimize the stress of your dog during examinations and procedures, and expert personnel will closely monitor your dog during the entire time. This study does not include the use of sedation. Should your animal experience excessive stress, the procedure will be interrupted and your dog will be excluded from the study.

Study Costs and Compensation:
Physical examination, echocardiography (heart ultrasound), blood analysis, and thoracic radiographs required by the study will be performed at no cost. The study drug (or placebo) will be provided at no additional cost. The owner will still be responsible for the cost of drugs other than the study drug, and for costs associated with any additional examination that will be deemed necessary by the clinician. The total value of the examinations offered at no cost in this package is more than $1700.

Confidentiality:
The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a

secure location; Ceva Santé Animale provides the study drug and the placebo at no cost, and will have access to study data.

Statement of Consent:
In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of _____ .
(Animal's name)

Owner or Agent Name (Printed): _____ Date: _____

Owner or Agent Signature: _____ Date: _____

Attending Clinician Name (Printed): _____ Date: _____

Attending Clinician Signature: _____ Date: _____

Please don't hesitate to contact us if you have any questions or concerns about this study.
The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Veterinary Teaching Hospital
Virginia-Maryland College of Veterinary Medicine
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone: 540-231-4621

You will be given a copy of this form to keep for your records.