Veterinary Health Center
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Owner perceived quality of life and monetary value of combination therapy (spironolactone and benazepril hydrochloride) compared to conventional therapy (enalapril / benazepril and spironolactone alone) in dogs with progressive myxomatous mitral valve disease.

Study Purpose:

Cardalis (spironolactone and benazepril hydrochloride chewable tablets) has recently received FDA certification for use in dogs with congestive heart failure secondary to myxomatous mitral valve disease (MMVD). With recent studies demonstrating clinical efficacy and positive effects on cardiac remodeling in patients with congestive heart failure, the addition of Cardalis is appealing, even more so when taking owner compliance into consideration. Quadruple therapy, endorsed by the ACVIM in the MMVD consensus statement in 2019, includes the utilization of pimobendan, furosemide and sequential blockade of the renin-angiotensin-aldosterone system with an ACE-inhibitor (enalapril / benazepril) and an aldosterone antagonist (spironolactone). With more drugs comes poor compliance which can lead to poorer clinical outcomes and lower client satisfaction. Cardalis effectively provides one half of the ACVIM quad-therapy for congestive heart failure secondary to MMVD and one would expect would provide a more pleasant and effective medication experience.

In an effort to promote familiarity and comfort in utilization of Cardalis in MMVD patients, Ceva Animal Health is offering funding for cardiologists for use of the medication in their MMVD patients for four months. In tandem of this opportunity, the goal of our proposed study is to evaluate our owner's compliance and perceived effect on quality of life for both their pet and themselves as the caregiver compared to administration of an ACE-inhibitor and spironolactone separately. In addition, clients will be surveyed regarding whether the potential benefit of a combination medication is valued above the increased monetary commitment. Our hypothesis is that owners will report improved quality of life (for both themselves and the patient), although when confronted with the monthly cost of the medication, the majority will opt for discontinuation of Cardalis due to cost despite the perceived improvement in quality of life compared to use of an ACE-inhibitor and spironolactone separately.

Eligibility:

- Dogs with a confirmed diagnosis of myxomatous mitral valve disease (ACVIM Stage B2) with signs of progressive left heart dilation whom are already receiving both enalapril and spironolactone.
- KSU VHC canine patients presenting for their routine cardiac evaluation will be considered for study participation.

Clinical Protocol:

If your dog is eligible and you decide to participate in the study, the following will occur. At the time of enrollment, an echocardiogram and renal profile will be performed as part of his/her routine cardiac evaluation. Any patient with a clinically significant azotemia noted on renal profile will be excluded from participating. Eligible patients will be switched from enalapril and spironolactone to Cardalis on enrollment. Owners will be surveyed regarding the health-related quality of life (hrQOL) for both themselves and the patient using the Owner hrQOL questionnaire and the Functional Evaluation of Cardiac Health (FETCH) questionnaire respectively. Owners will administer the study supplied Cardalis once a day, as instructed, for a 4-month period. *Owners will continue administering additional prescribed medications (e.g., pimobendan) as instructed by your veterinarian / cardiologist. Please refer to the discharge summary from today's visit for any additional study related information.* At the end of the 3-month period, patients will return for their next routine cardiac evaluation for a recheck echocardiogram and renal profile. Owners will again complete the health-related quality of life questionnaires provided by the study. Additionally, owners will be provided the estimated monthly cost of the medication and surveyed whether they would elect to continue with the new treatment regimen after the 4-month trial ends. In the event owners elect to revert back to the previous quad-therapy, they will be surveyed regarding their primary reason(s) and/or what reasonable cost range they would value the new treatment regimen for them to continue. Your participation in this study will end after administering Cardalis for the 4-month duration.

Fees for Services:

There is no cost associated with participating in this study. The 4-month supply of Cardalis was provided by the sponsor free of charge, in an effort to promote this new FDA approved medication for dogs with myxomatous mitral valve disease. You will not be paid for allowing your dog to participate in this study. Furthermore, you are responsible for the costs associated with the routine cardiac evaluations including the echocardiogram, renal profile and any additional testing or treatments as recommended by the attending clinician.

Owner Responsibilities:

You will be responsible for administering Cardalis as prescribed by the study veterinarian for a 4-month period. Please refer to the discharge summary from today's visit for any additional information related to the study. You will need to return to KSU VHC in 3 months for your next routine cardiology appointment. As part of the study, you to complete the hrQOL and FETCH surveys at enrollment and again at the 3 month appointment. You will need to notify the study doctor immediately, if you notice any new or worsening symptoms. Once the 4-month trial ends, you will need to decide if you will continue the Cardalis treatment or revert back to the conventional therapy (enalapril / benazepril and spironolactone alone).

Contact Information:

Please contact Kris Richardson, Clinical Trials Coordinator at the Veterinary Health Center, for more information about this study. Phone: (785)-532-3046; email: ClinicalTrials@vet.k-state.edu