

Research Subject Information and Consent Form

Title of Study: Clinical Trial of Cisterna Chyli Ablation and Pericardectomy for Treatment of Chylothorax in the Dog

Study Investigator: Jonathan F. McAnulty DVM, Ph.D.

You are invited to participate in a research study designed to determine the effectiveness of two new surgical procedures for the treatment of chylothorax disease in the dog. These procedures are performed **in addition** to the standard surgical procedure most commonly used to treat chylothorax (thoracic duct ligation procedure). Thus, in entering this trial your dog will still receive the potential benefits achieved with the current standard of treatment for chylothorax. The new surgery procedures to be studied here are 1) cisterna chyli ablation and 2) pericardectomy. These procedures are unlikely to have any negative effects on the results obtained with the standard thoracic duct ligation and, based on preliminary clinical and experimental data, may have positive benefits in terms of increasing the chances of resolving the chylothorax in your dog. Participation in this study is completely voluntary. You are invited because your dog has spontaneously occurring idiopathic chylothorax. In summary, if you are eligible to participate and agree to participate, about half of the dogs in the study will receive treatment by the combination of thoracic duct ligation and cisterna chyli ablation and half the dogs will receive a combination of thoracic duct ligation and pericardectomy. Approximately 60 subjects will participate in this study, all of whom will be at UW. The main risks of this treatment are known risks of any surgery such as wound complications, bleeding or anesthetic reactions.

Background: Spontaneous idiopathic chylothorax occurs in both dogs and cats in the absence of surgical or accidental trauma or any other obvious causes. Its cause is poorly understood and treatment can frequently be unsatisfactory. In the dog, the current standard treatment of chylothorax is by ligation of the thoracic duct using imaging with contrast lymphangiography to assure complete ligation. Subsequent case series utilizing this method established that success in resolving the chylothorax in dogs with thoracic duct ligation was about 53%. Other treatments have been proposed but have been no better and in some instances had worse results than thoracic duct ligation alone. Thus, this procedure currently remains the standard surgical treatment for this disease. There has been a significant lack of innovation in the treatment of chylothorax since 1990. However, recently two new procedures, cisterna chyli ablation and pericardectomy, both combined with thoracic duct ligation, have been introduced and represent new conceptual approaches to the treatment of chylothorax. Cisterna chyli ablation focuses on creating an environment conducive to the formation of lymphaticovenous anastomoses outside of the pleural space. Pericardectomy is based on the hypothesis that venous occlusion is responsible for continued chylothorax. Both of these new procedures have been reported in small case series to result in improved results over thoracic duct ligation alone. However, these treatments have not been examined in larger clinical trials in an objective manner at this time.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to objectively evaluate the efficacy of either cisterna chyli ablation or pericardectomy when added to thoracic duct ligation for surgical treatment of chylothorax in the dog. This study will determine if these additional procedures will improve on the efficacy of thoracic duct ligation and if either approach is significantly better and thus provide a new standard of treatment of this disease in the dog.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research study, your dog will be treated by ligation of the thoracic duct and in addition have either pericardectomy or cisterna chyli ablation procedures performed using the same incisions that are made for the thoracic duct ligation procedure alone. Your participation will last approximately one year. During this time, reevaluation by examination and chest radiographs will be performed.

ARE THERE ANY RISKS?

There have been no adverse reactions in animal studies of this modified surgical procedure relative to the risks encountered in the routine ligation of the thoracic duct or in routine pericardectomy for other disease processes. However, you must understand that any surgical procedure carries some degree of risk. Surgical risks that must be considered include wound complications (infection, serum accumulation, wound disruption), bleeding, pneumothorax, and the risks inherent to general anesthesia. If side-effects or complications were to occur, treatment will be available if needed.

ARE THERE ANY BENEFITS?

Your dog may or may not benefit directly from participating in this study. Your dog may benefit if the modified surgical procedure proves to have improved results over thoracic duct ligation alone. If the additional procedures do not provide enhanced effectiveness in control of chylothorax, your dog will, at a minimum, have received any benefits obtainable from the standard surgical treatment of chylothorax (thoracic duct ligation). Regardless, your participation in this research will benefit other animals and people in the future by helping us learn more about how chylothorax can be effectively treated.

ARE THERE ANY COSTS?

As a participant in this study you will be responsible for all costs associated with the treatments that are given to your dog at the UW-VMTH. In appreciation of your participation, \$2000.00 credit will be applied to your balance at the end of your dog's hospital stay.

ARE THERE ANY ALTERNATIVES?

You do not have to participate in this study to receive treatment for your dog's chylothorax disease. Alternatives to participating in this study include thoracic duct

ligation alone, other surgical procedures, dietary manipulation and various drug treatments. None of these treatments have been shown to improve on the results of thoracic duct ligation but may control the chylothorax in 50% or less of the animals so treated.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

There is no payment for your participation in this study other than a \$2000.00 cost relief that will be applied to your bill.

WILL THERE BE COMPENSATION FOR INJURY?

The grant funded by the Morris Animal Foundation to support this study will provide \$2000.00 in cost relief in appreciation of your enrolling your dog in this study. Any costs beyond this, regardless of whether they are incurred in the normal course of treatment or if they are incurred in treating any complications that may arise, will be borne by you.

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND?

Your decision to participate in this research is entirely voluntary. You may choose not to participate. If you do decide to participate, you must realize that the fact that once the surgery has been performed that this cannot be reversed. However, you may change your mind at any time and withdraw from further participation in the study without penalty or loss of benefits that you had prior to the study. You will be told of any new and significant findings of the study, as the data is analyzed at periodic intervals, which may affect your willingness to continue.

WILL MY CONFIDENTIALITY BE PROTECTED?

Researchers for this study might use information learned from this research in scientific journal articles or in presentations. None of this information will identify you personally.

WHAT IF I HAVE QUESTIONS?

If you have questions about this research, please contact the study investigator, Dr. Jonathan McNulty DVM, Ph.D. through the UW-VMTH at 608-263-7600.

Authorization to participate in the research study:

I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.

Signature of owner or agent for pet

Date