Virginia-Maryland College of Veterinary Medicine

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Veterinary Teaching Hospital
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Clinical Research Project
Client Consent Form

Study Title: Optimizing radiation therapy planning using advanced imaging in dogs with soft tissue sarcomas
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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.

Study Purpose:
Imaging studies have become an integral part for the diagnosis and the therapeutic decisions for cancer patients in veterinary medicine. Computed tomography (CT) and magnetic resonance imaging (MRI) are standard of care in humans for the diagnosis and the determination of their cancer's extent. Radiation therapy (RT) is used to treat soft tissue sarcomas in combination with surgery or alone in in both people and canine patients.

Advanced techniques have been developed in Radiation Therapy to improve RT planning with the ultimate goal to maximize dose delivery to the target (cancer) while sparing the normal surrounding tissues. Specific software has been developed that use CT images to create a 3D image of the patient's anatomy in order to define the target and the normal surrounding tissue, and to create a 3D RT plan which will meet the goals of maximum dose delivery to the target without damaging the normal tissue. MRI is potentially superior to CT in characterizing soft tissue sarcomas because of its ability to distinguish difference in soft tissues, but direct clinical comparisons have not been performed in the dog.

The purposes of this study are a) to investigate if there are differences on tumor imaging between computed tomography (CT) and magnetic resonance imaging (MRI) in dogs with soft tissue sarcomas and b) how these differences affect the radiation therapy planning and therefore local tumor control when radiation therapy (RT) is applied before or after surgery.

The study is not experimental. All procedures are standard of practice/care.

Study Design/Procedures:
Dogs with cytologically or histologically confirmed superficial soft tissue sarcoma are eligible for the study. You are offered the standard work up (staging) to assess the extent of the tumor and overall health for your dog. This includes blood work, computed tomography (CT) of thorax, abdomen and region of interest, and tumor biopsy. Magnetic resonance imaging (MRI) will be added as part of the work up.

Computed tomography and MRI are standard diagnostic non-painful procedures for dogs. General anesthesia is applied as standard method in order to immobilize the animal during CT and MRI. For the tumor biopsy your dog will be under general anesthesia and post biopsy pain medication will be offered as needed. MRI will add one (1) hour to the overall anesthesia time.

The work up is a one-day visit. Your dog will be discharged to you the same day after full recovery from anesthesia. We will discuss and offer standard treatment options for your dog at that day or after we have the results from all examinations.

Risks and Benefits:
The MRI procedure itself is a standard procedure for a number of tumors in our Hospital, but is not routinely offered in combination with CT due to cost. MRI will add useful information for treatment planning by characterizing better the extent

of superficial soft tissue sarcomas.

Although all procedures described above are routinely used as the part of the standard of care for animals diagnosed with cancer in our hospital, unexpected adverse events from the anesthesia or the biopsy may rarely occur. Potential side effects of these procedures include skin irritation and infection at the tumor biopsy site, and anesthetic complications such as your dog stopping breathing or its heart stop beating. Extremely rarely, general anesthesia may result in death.

Study Costs and Compensation:
The study will cover the cost of the CT, MRI, including contrast agents, general anesthesia, and tumor biopsy and histopathology. The estimated financial benefit to you, the owner is about $3,000. All additional costs (screening visits, bloodwork, cancer treatments) are not covered by the study and are the responsibility of the owner.

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; only researchers will have access to the records.

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 Signature: _____ Date: _____

Owner or Agent Printed Name: _____

Attending Clinician Signature: _____ Date: _____

Attending Clinician Printed Name: _____

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.