Clinical Research Project
Client Consent Form

Study Title: The impact of neoadjuvant prednisone on grade and proliferation indices in canine cutaneous mast cell tumors: A pilot study
Principal Investigator: Shawna Klahn, DVM, DACVIM (Oncology)
Veterinary Clinical Research Office 540-231-1363 or vettrials@vt.edu

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:

Mast cell tumors are the most common malignant skin tumor in dogs. The prognosis is highly-dependent upon the tumor grade, which can only be determined by histopathology (biopsy). For low-grade tumors, complete surgical removal is curative. However, nearly 100% of dogs with high-grade tumors will succumb to their disease within 6 months to a year of diagnosis. Treatment with prednisone is an effective treatment as sole therapy. It is also used prior to surgery to shrink the tumor or as part of a chemotherapy protocol used in dogs with high-grade tumors. However, it is unknown how the use of prednisone prior to surgery affects the factors used to define the tumor grade, which has potential to impact the prognosis and recommended further treatment options.

The purpose of this study is to determine how pre-surgical prednisone affects the grading and proliferation indices in canine mast cell tumors.

Study Design/Procedures:

Criteria for selection

You were selected as a possible participant because your pet has been diagnosed with a mast cell tumor.

Your pet may qualify for this study if:
1. Your dog is larger than 11 lbs (5 kg) of body weight.
2. Your pet has no other serious, life-threatening illness (heart, liver, or renal failure).
3. Your pet has not received any treatment for the mast cell tumor, including chemotherapy, corticosteroids, tyrosine kinase inhibitors, or radiation. Previous removal with recurrence is allowed as long as no treatment to the current tumor has occurred.
4. Your pet’s bone marrow, kidney, and liver function are considered adequate based on a complete blood count and serum chemistry profile.
5. A diagnosis of mast cell tumor has been confirmed by a veterinary pathologist.
6. The mast cell tumor is at least 1cm in diameter, but less than 10cm in diameter

Procedures

If you agree to participate in this study we will perform the following procedures:
Eligibility evaluation

To determine eligibility for enrollment into the study, your pet will need to undergo the following tests. Comparable laboratory and cytopathological evaluation performed at another veterinary clinic within 7 days of VMCVM Oncology consultation is allowable.

1. Complete physical exam
2. Lab work: We will obtain blood samples from your pet for a complete blood count and chemistry profile. Four to six mls (about 1 teaspoon) of blood will be collected from a vein in your pet's neck, which is the easiest access point. We will also collect 5 mls of urine, either through cystocentesis or free catch. These are the standard methods for obtaining blood and urine at the Veterinary Teaching Hospital.
3. Fine needle aspirate cytology of the tumor: A definitive diagnosis of mast cell tumor must be obtained. A needle aspirate following pre-treatment with diphenhydramine (Benadryl®), performed without sedation or under light sedation, may be submitted for evaluation by a Board-certified veterinary pathologist.

Pre-treatment biopsy and prednisone treatment

Within 7 days of enrollment, your pet will undergo and begin the following:

1. Incisional (small) biopsy of the mast cell tumor
2. Histopathological tumor evaluation and determination of proliferation indices levels
3. Oral, at-home treatment with daily prednisone for 10-14 days

Biopsy procedure: A small piece of your pet's tumor will be removed under heavy sedation for evaluation by a veterinary pathologist. This is an out-patient procedure and you can expect to take your pet home the same day.

Post-treatment mast cell tumor removal

Within 10-14 days of starting treatment with prednisone, your pet will undergo surgical removal of the mast cell tumor. This will be performed by a Board-certified Veterinary Surgeon under general anesthesia monitored by a Board-certified Veterinary Anesthesiologist in our Veterinary Teaching Hospital. A complete removal (wide excision) will be attempted in all cases, if deemed possible by the surgeon. The tumor will be submitted for diagnosis, tumor grading, and measurement of the proliferation indices levels.

Follow-up

Once your pet is discharged from surgery, your participation in the study is completed. Once the biopsy results are finalized, you will receive a phone call informing you of these results. You will also receive recommendations for further tests or treatments by our Board-certified Veterinary Oncologists. There is no obligation to pursue any further testing or treatment.

Risks and Benefits:

The procedures performed and the medication(s) administered in this study are routine clinical procedures. There are no experimental procedures or medications.

Although unexpected, there could be complications with the biopsy or surgery procedures. These problems can be due to inflammation or infection and may result in bruising, incision dehiscence (opening of stitches), infection, and temporary pain. Biopsies are performed using sterile technique to reduce the risk of infection, and under heavy sedation with medications that have analgesic (pain control) properties. Mast cell tumor removal will be performed in a sterile operating room using sterile instruments and aseptic technique under general anesthesia. Patients will be monitored during the procedure by a trained anesthesia technician under the direct supervision of a Board-certified Veterinary Anesthesiologist. Your pet will recover in the Intensive Care Unit overnight, receiving pain medications and 24-hour monitoring and care.

The anticipated benefit of this study for your pet is determination of prognosis by tumor histopathology and proliferation indices, and tumor removal. Tumor removal is the mainstay of treatment for mast cell tumors regardless of grade. In addition, the study will cover the cost of the tumor biopsy (sedation, biopsy procedure, histopathology, proliferation indices), the cost of the prednisone treatment, and $1000 towards the surgical removal of the mast cell tumor. The value of these benefits is $1450.
Study Costs and Compensation:

Once informed consent is obtained, the study will cover the expenses for the pre-treatment biopsy, the prednisone treatment, and $1,000 towards the cost of surgery. This compensation will only partially cover the cost surgical removal. Typical cost of a skin mass removal in the Veterinary Teaching Hospital is $1800-2200. You are responsible for any other clinical fees associated with the surgery, any identified concurrent medical issues, or complications associated with surgery.

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 locked file; 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: ________

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.