OVC Ontario Veterinary College

OVC RESEARCH

Clinical Trials: Client Information Sheet

Evaluation of sentinel lymph node mapping in dogs with lung tumours using CT lymphography and intraoperative indocyanine green

Your participation in this clinical trial evaluating staging of dogs with lung tumours is greatly appreciated. Your animal's clinician will explain your animal's condition as well as treatment options available. If you choose to enroll your animal in this study, this Information Sheet will explain the purpose of the study, your responsibilities, patient procedures, and possible outcomes.

What are clinical trials?

Clinical trials are research studies used in all specialties of human and veterinary medicine to evaluate new medical devices, vaccines, diagnostic tests and treatments. These trials may investigate new types of surgical or other procedures as well as novel medical therapies for diseases. Your animal's clinician will discuss how your animal's condition is typically treated, and will explain other options available through current clinical trials. Clinical trials allow clinicians to discover new and improved ways to prevent, diagnose or treat diseases.

What is the purpose of this clinical trial?

In the field of veterinary oncology, identification of metastatic disease is critical for determining the extent of disease, prognosis, and for developing treatment plans. For many cancer types, metastasis occurs via the lymphatic system and the status of the draining lymph nodes is an important part of the pre- and intraoperative evaluation. The sentinel lymph node (SLN) is the primary lymph node draining the tumour and although one might expect that it is the first lymph node downstream from the tumour, this is not always true. Failure to identify and assess the sentinel lymph node can lead to incomplete treatment, worse prognosis and poor patient outcome. Currently in veterinary patients, there are not good protocols in place to identify sentinel lymph nodes. The development of these protocols could help us to decrease the number of lymph nodes we remove, in addition to ensuring we are accurately evaluating the most important lymph node for making follow-up treatment recommendations.

What is the study goal?

The objective of this study is to evaluate a new technique for imaging and intraoperative techniques for identification of sentinel lymph nodes. A secondary objective is to develop a protocol for these techniques in veterinary patients with lung tumours.

Which patients are eligible to participate in this study?

Patients with a confirmed diagnosis of a lung tumour undergoing staging and surgery are eligible for enrollment in this trial. Other specific criteria required to be included in this study include that the patients must be undergoing a CT scan for surgical planning of tumour and lymph node removal.

What happens to my animal in this clinical trial?

The commitment to participate in this study is no different than if your pet was undergoing a CT scan and surgery for their tumour. In this study, we are considering what is already standard of care (CT and surgery) and trying to improve this process. For the CT scan, in addition to receiving a contrast agent intravenously, as is always performed for these cases, we will also inject a similar agent locally. With this injection, we will attempt to identify the lymph node that first drains the tumour, also known as the sentinel lymph node. This information will be compared to our findings in surgery and on histopathology when the tissues are submitted. Following the procedure, your pet will be monitored for several hours to ensure they do not develop any complications from the injection. Surgery will be planned for within 1 week of the CT scan and may be as soon as the day following.

Time Commitment

For this study, your pet will present for the CT scan as is routinely arranged by the oncology service. You do not need to make any changes to your plans or expectations. Your pet will then return for surgery following routine planning. To be included in the study, your pet must have surgery within 1 week of the CT scan to ensure that no major changes in the tumour growth have occurred.

How long will my animal be involved in this clinical trial?

This study will be completed with 2 weeks as part of your pet's standard preoperative and surgical treatment for their tumour.

Are there any side effects or risks for participating in this clinical trial?

For the CT lymphangiogram, there is a small risk of developing mild leakage of air from the injection site in the lung. To monitor for this side effect, we will monitor your pet's breathing closely after the CT scan and perform an x-ray to ensure there is no evidence of air developing in the chest cavity. If necessary, we will drain any persistent air as needed. The contrast agent that will be injected is regularly used intravenously (injected into the vein) for the imaging study and we would expect that with the local injection there will be very little absorbed into the vessels. For the surgical aspect of the procedure, methylene blue and indocyanine green are regularly used in our institution for lymph node evaluation in oral tumors. These agents are also used in humans for sentinel lymph node biopsy. No side effects have been documented in any of our patients when we have injected these agents into the space around the tumour. The biggest risk (which is indirect) is that we are unsuccessful in either identify or sampling a lymph node, which is possible as this technique is anticipated to be more challenging in this region.

Can I withdraw my animal from this clinical trial?

You are free to withdraw your animal from this clinical trial at any time, and this decision will not influence your animal's medical care. You will not be charged for any of the elements that were compensated for the study but you will not receive the additional credit towards your bill. Please contact your animal's clinician or the study contact person as soon as possible if you are considering withdrawing your animal from this trial, so that an alternative treatment plan can be created.

Are there any financial or other benefits to participating in this clinical trial?

To be included in this study, your pet will undergo a standard CT scan and surgery, as would be performed if they were not involved in the study. Direct compensation is not included for this standard of care treatment but there is a credit applied to your account if you pet completes the study. The main benefit is that your pet will receive a more detailed CT scan to help with evaluation of the tumour at no additional cost. The cost of anesthesia during the specialized CT portion (~1/2hr), a chest xray after the CT, as well as the cost of the contrast agents, and the specialized camera to view the contrast during surgery is covered by the study (~$1500 total cost). In addition, if your pet completes the study you will be provided with a $1000 credit on your account.

Are there any benefits to my animal, other animals and/or the veterinary community, society?

By participating in this study, your pet will help to develop protocols to better diagnose and treat dogs with lung tumours in the future. In addition, by gathering this information, it will be able to be applied to animals with various other tumour types. The results of this study will be published and made available for the benefit of the scientific community. With this publication, you, nor your pet, will be identified. Finally, Dr. Oblak is working closely with human researchers that hope to apply these techniques for surgery in humans with lung tumours.

What are my responsibilities if I choose to participate in this clinical trial?

You will be responsible for bringing your pet to the OVC-HSC for both the CT scan and surgery (may occur during the same visit). In addition, you are expected to pay for the standard costs for the preoperative staging, including the CT scan and surgery for removal of the tumour and lymph nodes. Like any medication, the clinical trial treatment may have a low rate of side effects. This study does not cover the costs of hospitalization or other costs associated with complications related or unrelated to the clinical trial.

You are expected to return to the Ontario Veterinary College for follow-up appointments as outlined by your clinician and the clinical trial protocol.

How is this study funded?

The costs of this study are supported by the OVC Pet Trust Fund and the Animal Health Partners Research Chair in Veterinary Medical Innovation

Who do I contact if I have further questions?

Please feel free to contact your clinician or the study investigator(s) if you have any questions:

Dr. Michelle Oblak, moblak@uoguelph.ca

In case of emergency, contact the Ontario Veterinary College at (519) 823-8830 or your referring veterinarian immediately.