VIRGINIA TECH
ANIMAL CANCER CARE AND RESEARCH CENTER

THOP chemotherapy protocol as front-line treatment of canine B-cell lymphoma

Purpose

To determine the efficacy and side effect profile of THOP, a new multi-drug chemotherapy protocol, as the first-line treatment in dogs with diffuse large B-cell lymphoma

Background

Lymphoma is one of the most common cancers diagnosed in dogs. The current standard of care for treatment is a chemotherapy protocol that uses multiple drugs: doxorubicin, vincristine, cyclophosphamide, and prednisone. This protocol, the UW-19, requires weekly clinic visits for 19 weeks, and is the most effective treatment available: >85% of dogs experience a complete clinical remission (all enlarged lymph nodes return to normal size). However, canine lymphoma is rarely cured: less than 10% of dogs are alive at two years after diagnosis. Half of dogs treated with the UW-19 will have a complete remission for longer than 8-10 months. However, the remission time is measured from the date of diagnosis to the date of cancer progression, which includes the 5 months of treatment, resulting in 3-5 months of life in remission after finishing the treatment protocol. Multiple attempts to reduce the treatment time using the same combination of drugs have failed.

Our team proposes a different strategy: replacing the least effective drug in the UW-19, cyclophosphamide, with a more effective drug, temozolomide. We will reduce the total treatment time from 19 weeks to 15 weeks by giving temozolomide at the same time as doxorubicin. Temozolomide has been shown to be work well alongside doxorubicin, and to be effective in dogs whose lymphoma does not respond, or stops responding, to standard of care protocols, like the UW-19. The objective of our study is to determine the efficacy and side effect profile of THOP, a new multi-drug chemotherapy protocol, as the first-line treatment in dogs with diffuse large B-cell lymphoma (DLBCL). This approach will reduce the treatment time by 4 weeks and the overall cost of treatment by more than $1,000.

This study is funded by the Veterinary Memorial Fund.

Eligibility

- Confirmed diagnosis of multi-centric diffuse large B-cell lymphoma
- At least 1 year old and weighing at least 10kg / 22lbs.
- Adequate organ and bone marrow function to safely receive treatment with chemotherapy
- Owner willingness to comply with study requirements

Exclusion Criteria

- Dog cannot have received cancer-directed therapy other than prednisone (5 day course or less)
- Stage 5 lymphoma (i.e. bone marrow, lung, kidney, eye, gastrointestinal tract, skin, or other non-lymphoid organ involvement)
- Dog must be expected to live for at least 4 weeks even if s/he were to receive no treatment or only supportive, palliative care
- Significant heart dysfunction (arrhythmia or weak pumping)

Study Design

This study takes place at the Animal Cancer Care and Research Center in Roanoke, VA.

Before beginning treatment, your dog must undergo the following tests to determine if s/he is a good candidate: Lab work, biopsy, chest x-rays and abdominal ultrasound. Once your dog is enrolled in the study, there are (15) protocol clinic visits which include (10) chemotherapy treatments, (2) imaging visits, and (15) blood draws. (See below)

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Study visit summary

Procedures by week	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Vincristine i.v.		x			x			x			x			x		
Doxorubicin i.v.			x			x			x			x			x	
Temozolomide oral, at home once a day for 5 days			x			x			x			x			x	
Prednisone oral, at home once a day for 7 days		x			x			x			x			x		
CBC	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Chemistry panel	x		x			x			x			x			x	
urinalysis, immunophenotype, and diagnosis	x															
Thoracic radiographs, abdominal ultrasound	x						x									x

Your dog will need to return to the Oncology service once a month for an exam after all 15 weeks have been completed. At each recheck visit, your pet will have a physical exam, and additional diagnostics if indicated. We ask that you keep the clinical oncology service and researchers informed on the status of your pet's health. If relapse (progression of the lymphoma) is suspected, it will be confirmed by fine needle aspirate and official pathologist review (cytology). At that time, we will discuss additional treatment options and prognosis.

Compensation

Enrollment in the study will provide the temozolomide at no charge, a compensation of approximately $1,000 if the protocol is completed as planned. All other costs associated with THOP treatment and monitoring are out-of-pocket, including the screening (eligibility) tests, imaging exams, clinic or hospital visits for medical management of side effects, and follow-up visits. All diagnostics or procedures are standard, and would be performed in any pet dog undergoing evaluation and treatment for lymphoma with chemotherapy; there are no additional tests or procedures required due to study involvement. The out-of-pocket costs may vary during the study period, and the cost of treatments vary based on the drug that is given and your dog's weight. Estimates of screening tests, treatment visits, and imaging visits (chest x-rays and abdominal ultrasound) will be calculated specifically for your pet and provided at the time of screening. You are responsible for any other clinical fees associated with medical complications of the THOP therapy or other medical problems.

Contact

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If your query is urgent, please call the Animal Cancer Care and Research Center on (540) 526-2300.