A multi-center, prospective, randomized, open label clinical trial in dogs with osteosarcoma treated with the Standard of Care followed by orally administered mTOR inhibitor Rapamycin

Purpose

To evaluate the safety and effectiveness of Standard of Care therapy, followed by rapamycin administration in dogs with osteosarcoma.

Background

In both human and canine patients with osteosarcoma (OSA), there is a substantial risk that the disease will spread to the lungs. Lung metastasis is the leading cause of mortality for patients with this disease. The protein mTOR plays an important role in progression of many cancers. We are testing whether targeting the metastatic potential of cancer cells by inhibiting mTOR can reduce the risk of metastatic progression for patients with OSA. The investigational agent in this study is rapamycin, an inhibitor of mTOR.

Eligibility

- Otherwise healthy dogs with histologically or cytologically confirmed diagnosis of osteosarcoma
- Measurable disease that can be removed via amputation surgery
- Dogs receiving pain relievers including NSAIDs, gabapentin, or tramadol are eligible

Exclusion

- Dogs < 25 kg in size
- Metastasis based upon physical exam, thoracic radiographs, and abdominal ultrasound
- ANY prior therapy for osteosarcoma (chemotherapy, radiation, or bisphosphonates)
- Significant health conditions, including kidney or liver problems, history of congestive heart failure, or blood clotting disorders

Study Design

Eligibility for the trial is determined by chest x-rays, routine lab work (CBC, chemistry, urinalysis), abdominal ultrasound, and fine needle aspirate cytology and special stain (ALP) of the lesion. Dogs will undergo amputation and receive four doses of Carboplatin chemotherapy starting 10-14 days post-op. This is standard of care for osteosarcoma. At the first chemotherapy visit, dogs will be officially enrolled and considered on-study, and randomized to either the standard-of-care arm or to the experimental arm (the drug rapamycin). All of these procedures must all be completed at the Vet School in Blacksburg, VA. If randomized to the rapamycin arm, rapamycin must be administered by the owner at home on a schedule provided by the study investigator. Monthly overnight monitoring visits are required for dogs taking rapamycin. Dogs in the standard-of-care arm will be monitored every eight weeks until metastasis.

Compensation

Screening costs are approximately $700, unless additional diagnostics are required in specific cases, and are not covered by the study. The study will reimburse $1,215 once the dog is enrolled and will cover the costs of all the chemotherapy treatment visits. Estimated total surgery cost is approximately $2,500 for uncomplicated cases. For dogs randomized to the rapamycin arm, the cost of rapamycin treatments and monitoring visits are covered by the study. For dogs in the standard-of-care arm, the first three monitoring visits are covered.

Contact

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If your query is urgent, please call the Small Animal Hospital (540) 231-4621 and ask for the oncologist on duty.