Histotripsy for treatment of canine appendicular osteosarcoma

Purpose
To determine if histotripsy, a novel treatment that can destroy tissue without radiation or heat, can effectively treat canine osteosarcoma.

Background
Osteosarcoma (OS) is the most common bone cancer in dogs. Typically, OS is treated with a combination of surgical removal of the primary tumor and chemotherapy for metastatic disease. Surgical removal of the tumor usually involves limb amputation or limb salvage surgery. Limb salvage surgery can have high complication rates, and not all dogs are suitable for limb amputation. Even though chemotherapy delays metastatic disease development, most dogs with OS ultimately succumb to metastasis.

Histotripsy is a novel treatment that mechanically breaks down tissues and can potentially induce the immune system to attack cancer cells. This study aims to evaluate the efficacy of histotripsy to treat dogs with OS, to ultimately advance the development of histotripsy as a non-surgical limb salvage treatment option for OS and an immunotherapy treatment against metastatic disease for OS.

Eligibility
- Dogs of any age, weight, sex, or breed diagnosed with appendicular osteosarcoma via cytology or biopsy
- Owners have elected standard-of-care treatment for osteosarcoma – limb amputation and chemotherapy (chemotherapy may be administered at another veterinary facility)
- Free from other systemic illness

Exclusion Criteria
- Dogs will undergo limb amputation as part of this study. Dogs who have already had amputation or tumor resection are not eligible to enroll.
- Dogs who have received any tumor-directed therapy (e.g. radiation) or immunosuppressive drugs prior to study enrollment
- Evidence of metastatic disease

Study Design
Dogs will be evaluated for eligibility at the Animal Cancer Care and Research Center in Roanoke, VA.

Qualifying dogs will undergo a non-invasive histotripsy treatment of the tumor 1-5 days prior to standard-of-care limb amputation surgery. Travel will be required to the Veterinary Teaching Hospital in Blacksburg for the histotripsy treatment. Tumor samples will be obtained after limb amputation and evaluated by a pathologist at Virginia Tech. Results from this routine evaluation will be provided to you. Enrolled patients will need to return to the Animal Cancer Care and Research Center in Roanoke, VA for recheck visits at 2 weeks, and 3, 6, 9 and 12 months after surgery.

Compensation
Histopathological diagnosis of your dog’s tumor will be provided to you at no cost, and there will be no charge for the recheck visits. Up to $2,000 of the cost of surgical limb amputation will be covered by the study. $200 will be applied towards the final visit to owners who complete all four scheduled recheck visits. Total out of pocket costs for owners are estimated to be between $2,000-3,500.

Chemotherapy treatment is recommended as part of the standard-of-care treatment for dogs with osteosarcoma, and has been shown to improve outcomes for affected dogs. The cost of chemotherapy is not covered by the study.

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