THE OHIO STATE UNIVERSITY

VETERINARY MEDICAL CENTER

Immunotherapy for canine oral melanoma

Oral melanoma is a highly aggressive disease with poor outcomes and no effective treatments. Our recent research has shown that a weakened form of the lymphocytic choriomeningitis virus (LCMV) is safe and can trigger strong anti-tumor effects.

By injecting a small amount of this weakened virus directly into the tumor, we aim to activate the dog's immune system to fight the cancer. Additionally, we will collect and expand immune cells from the tumor, as these cells are more likely to recognize and attack cancer cells. These enhanced immune cells will then be reinfused into the patient to target existing or potential metastatic disease.

To evaluate our therapy, we will first perform a tumor biopsy to confirm the diagnosis and analyze the immune cells already present (Tumor infiltrating lymphocytes). We will then inject the tumor with the weakened virus. One week later, the tumor will be surgically removed, and immune cells from the cancer will be expanded for future use if metastases are present or develop later. After treatment, we will closely monitor the patients through periodic blood tests and imaging (CT scans) every three months.

A small group of dogs (randomly selected) will be the control, and while not receiving the virus injection, they will have their immune cells extracted from the tumor and expanded to be reinfused in case of progressive disease.

Client Compensation:

Once a dog is screened and deemed eligible for the study, we will cover the costs of the tumor biopsy, two to three CT imaging sessions, all study-related blood work, the viral reagent, as well as the extraction, expansion, and reinfusion of immune cells.

Additionally, participating dogs will receive an \$800 incentive.

Potential Medical Benefits:

Potential medical benefits include longer disease remissions after surgical removal of the primary tumor, slowing down or remission of metastatic disease.

Potential Medical Risks:

Following tumor biopsy: bleeding, infection of tumor, welling, redness, pain, fever, and/or discharge/pus/odor at the biopsy site.

Following virus injection and reinfusion of immune cells: skin rash, fever, lethargy, anaphylaxis.

What qualifies my pet for enrollment?

Inclusion Criteria:

Dogs that are otherwise healthy with localized cytologically or histologically confirmed melanoma will be recruited to the study.

Tumors need to be easily accessible to percutaneous injection and needle biopsy.

Exclusion Criteria:

Dogs with a history of immune deficiency or requiring immunosuppressive medications will be excluded. Dog received local radiation therapy to the primary tumor.

Diagnosis/Condition Being Studied: Oral melanoma

Intervention to Be Studied: Injection of weakened virus to the tumor and transfusion of tumor infiltrating lymphocytes

Contact: <u>CVM-ClinicalTrials@osu.edu</u>

If you believe your pet may be eligible for this study, please fill out a pre-screening questionnaire.

