

# Can short-term fasting produce a favorable tissue immune response to help fight cancer?

Blue Buffalo Clinical Trials Office

[CVM-ClinicalTrials@osu.edu](mailto:CVM-ClinicalTrials@osu.edu)

Cancer cells have a unique metabolism that is highly dependent on the abundance of glucose. Recent studies in mice have shown that calorie restriction slows cancer progression and improves response to chemotherapy. Other studies in dogs and people have also shown that short-term fasting can reduce chemotherapy side effects. It is not clear yet why this happens, but it is suspected that fasting positively impacts a patient's immune system and how it responds to their cancer. The purpose of this study is to learn more about how the tissue environment and immune responses that surround a tumor might be changed by short-term (48 hours) fasting.

Dogs will be screened at the screening visit (day -14 to day -1) and eligible dogs will be randomized and enrolled on Day 0 at which point a continuous glucose monitor and baseline clinical data will be collected; fasting, if applicable, will begin. All dogs will remain in hospital starting on day 0 through Day 2 during which blood, urine, feces and rectal and oral swabs will be collected. Day 2 (48 hours post fasting) will mark the completion of study participation and then care will be transferred to the surgical team for surgical excision per standard of care and discharge to owners.

The duration of the study is 48 hours.

## **Client Compensation:**

For dogs that meet all the criteria to participate, the cost of the initial biopsy, the hospitalization for the fasting period and all the related lab work and sample collection for the two-day study will be paid for by the study. These dogs and their owners will also receive \$500 to use toward their dog's cancer treatment at the OSU Veterinary Medical Center.

## **Potential Medical Benefits:**

Recent studies have suggested that fasting can change the tumor immune environment to be more favorable against the cancer. However, we don't have any data to suggest that your dog will clinically benefit from this fasting study. The goal is to develop new treatments and techniques that may benefit future patients.

## **Potential Medical Risks:**

Possible risks of concern would be:

- Low glucose (hypoglycemia) from short-term fasting (48 hours) is an uncommon risk in fasting adult dogs. Dogs will be monitored with a continuous glucometer (CGM) which will be scanned every 8 hours.
- Imaging: Low risk, dogs could develop kidney disease or hypersensitivity to the imaging contrast.
- Continued hemorrhage from the aspiration site of the fine needle aspiration or ultrasound-guided fine needle aspiration (low risk).
- Tissue biopsy is generally minimal but, in some cases, some bleeding and infection of the surgical site might occur. Additionally, dogs with appendicular osteosarcoma are at an increased risk for pathologic fracture of the affected limb secondary to their cancer.
- Urine collection from the urinary bladder using a needle (cystocentesis) is very infrequent. These include hemorrhage and bladder tear/rupture.
- Blood draws although rare, could include bleeding and bruising at the collection site.
- Sedation risks are not common and may include abnormal heart rhythms (arrhythmia), breathing problems, allergic reaction to the medicines and in rare occasions death.

## **What qualifies my pet for enrollment?**

### **Inclusion Criteria:**

Eligible patients (any breed of dog) must meet all the following:

- Confirmed diagnosis of osteosarcoma (OSA) or melanoma

# Can short-term fasting produce a favorable tissue immune response to help fight cancer?

## Blue Buffalo Clinical Trials Office

[CVM-ClinicalTrials@osu.edu](mailto:CVM-ClinicalTrials@osu.edu)

- Eligible for surgical excision of the primary mass
- Weigh > 15kg.
- Dogs with OSA that do not have a pathological fracture.
- Free of lung metastasis
- Deemed otherwise healthy at PI/Clinician discretion.
- Estimated life expectancy of 28 days.
- Completed washout period of 14 days if prior chemotherapy/radiation/related acute toxicities are present.
- Completed washout period of 14 days for antibiotics.
- No evidence of current metabolic disease (hypo or hyper adrenocorticoids, hypothyroidism, or diabetes)
- Adequate organ function as indicated by standard laboratory tests (CBC, Chemistry, Urinalysis)
  - Liver: Total bilirubin < 1.5X the institutional upper limit of normal (ULN), ALT < 3X ULN
  - Renal: Serum creatinine < 1.5X ULN

### Exclusion Criteria:

- Dogs with evidence of current metabolic disease (hypo or hyper adrenocorticoids, hypothyroidism, or diabetes)
- Dogs with any conditions that will contraindicate fasting (medications, gastric ulcer...)
- Dogs with liver or renal impairment as described in the inclusion criteria.
- Dogs receiving radiation or chemotherapy or who are experiencing acute toxicities who are unable to endure a 14-day washout period.
- Dogs weighing <15kg.
- OSA dogs with evidence of pathologic fracture
- Dogs whose primary tumor is not recommended for surgical excision.
- Dogs with a life expectancy that is <28 days.
- Dogs who are deemed ineligible at the discretion of PI/Clinician

**Diagnosis/Condition Being Studied:** Oral melanoma and Appendicular Osteosarcoma (osteosarcoma (OSA) of the limbs).

**Intervention Being Studied:** Tumor microenvironment, following short-term fasting, and whether tumors with different immune landscapes are impacted differently by these physiological changes.

### Primary Outcome:

Monitoring glucose changes through the fasting process, evaluating immune cell changes in circulation and in the tumor, gut biome changes, levels of serum ketone bodies, and levels of plasma IGF before and after fasting.

### Primary Outcome Measure:

Physical exams, blood glucose monitoring, and blood, urine, and fecal monitoring will be performed throughout the trial.

### Primary Outcome Endpoint:

To learn more about how the tissue environment and immune responses that surround a tumor might be changed by short-term (48 hours) fasting.

### Contact:

Email: [CVM-ClinicalTrials@osu.edu](mailto:CVM-ClinicalTrials@osu.edu)

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



**Pre-Screen  
HERE**