



NC State Medical Oncology is enrolling patients for a clinical trial of an experimental immunotherapy for the treatment of bladder cancer. The primary purpose of this study is to investigate the safety and immune-stimulating properties of a novel therapy being developed at NCSU. There will be multiple dosing groups during this study.

The immunotherapy uses an immune stimulant (called IL-12) mixed in a bio adhesive solution that allows it to stick to the bladder walls, including the cancer, and 'turn-on' anti-cancer immune cells just under the surface. *All dogs will receive immunotherapy.*

PARTICIPATION:

- 8-day study (Monday – Monday) at NC State Veterinary Hospital
 - Bladder immunotherapy under general anesthesia, day 1 (Mon)
 - Hospitalized for observation, days 1 – 3 (Mon – Wed)
 - Return for outpatient evaluation, days 4 (Thurs) and 8 (Mon)
 - Multiple blood and urine samples collected over study period
 - Quality of life questionnaires collected on days 1 and 8 (Mon, Mon)
- Pre-staging, immunotherapy and monitoring provided at no cost
- No placebo group – all dogs receive immunotherapy treatment
- Re-enrollment for additional immunotherapy doses is possible

ELIGIBILITY:

- Male or female dog, any breed, weighing at least 8 kg (17.6 lbs.)
- Urothelial cell carcinoma (UCC; also called transitional cell carcinoma)
 - Diagnosis via either cytology and BRAF test; or biopsy/histology
 - Muscle-invasive mass in bladder on ultrasound imaging
 - Metastatic UCC (e.g., lymph nodes, lungs) is permitted
- Criteria that exclude participation
 - Bloodwork abnormalities incompatible with immunotherapy
 - Poor quality of life due to cancer (e.g., urinary obstruction)
- Patients can be untreated, or have received prior therapy
 - One month or more since last radiation or chemotherapy dose
 - No other immunotherapy or prednisone treatment allowed
 - Non-steroidal anti-inflammatory drugs (NSAIDs) are permitted

For additional information contact the Clinical Studies Core:

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NC STATE College of Veterinary Medicine