Combining Immunotherapy and Radiation Therapy to Help Patients Avoid Bladder Removal After Treatment Shrinks Muscle Invasive Bladder Cancer, BRIGHT Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have histologic evidence of cT2-T4aN0M0 muscle invasive urothelial carcinoma of the bladder within 180 days prior to starting neoadjuvant therapy (NAT) * Participants must have had CT chest/abdomen/pelvis (C/A/P), MRI C/A/P or PET within 60 days prior to starting NAT to determine cT2-T4aN0M0 * Participants must have undergone TURBT with biopsy of areas of prior disease and systematic biopsies (left and right lateral, dome, posterior wall and trigone) and radiologic staging showing clinically T0-T1 disease within 60 days after the last dose of NAT * NOTE: This TURBT must be within 90 days prior to registration. Registration must be within 90 days after the last dose of NAT * Participants must have imaging of the chest, abdomen, and pelvis performed using CT or MRI preferably with contrast. Fludeoxyglucose F-18 (FDG) PET-CT can also be used for staging. If FDG PET-CT is used, then it is at the discretion of the investigator if they want to additionally obtain diagnostic CT or MRI with contrast within 60 days after the last dose of NAT * Participants with lymph nodes ≥ 1.0 cm in the shortest cross-sectional diameter on imaging (CT or MRI of abdomen and pelvis) after completion of NAT must have a PET-CT within 70 days prior to registration. A biopsy in the setting of negative PET-CT is not required unless there is strong clinical suspicion for nodal involvement with tumor. Participants with a positive PET are deemed ineligible unless a biopsy is performed and shows no evidence of tumor involvement * NOTE: For questions regarding the above eligibility criteria, please contact the study chairs in addition to the Southwest Oncology Group (SWOG) Statistics and Data Management Center (SDMC) * Participants must not have evidence of ≥ T2, N1-3 or metastatic disease after NAT * Participants must not have the presence of small cell, neuroendocrine carcinoma, plasmacytoid variants on any pathology * Participants must not have had urothelial carcinoma or histological variant at any site outside of the urinary bladder within 24 months prior to registration except Ta/T1/carcinoma in situ (CIS) of the upper urinary tract, including renal pelvis or ureter if the participant underwent complete nephroureterectomy * NOTE: Participants with mixed variant histology will be eligible for the trial if the majority (\> 50%) of the tumor is urothelial cell carcinoma * Participants must have received at least 3 and no more than 6 cycles of National Comprehensive Cancer Network (NCCN) guideline concordant NAT for MIBC * NOTE: Prior intravesical immunotherapy or chemotherapy for non-muscle invasive disease is allowed * Participants must not have had prior pelvic radiotherapy * Participants must not have had anti-PD-1, anti PD-L1, anti PD-L2 or anti-CTLA4 antibody, any other antibody or drug targeting T-cell co-stimulation, enfortumab vedotin, or any other drug targeting nectin-4 * Participants must not have received a live attenuated vaccination within 28 days prior to registration * Participants with conditions requiring immunosuppressive doses of steroids (\> 10 mg/day of prednisone or equivalent) or other immunosuppressive medications must not be taking steroids at time of trial registration * Participants must be ≥ 18 years old at the time of registration * Participants must have Zubrod performance status of 0-2 * Participants must have a complete medical history and physical exam within 28 days prior to registration * Leukocytes ≥ 3 x 10\^3/uL (within 28 days prior to registration) * Absolute neutrophil count ≥ 1.5 x 10\^3/uL (within 28 days prior to registration) * Platelets ≥ 100 x 10\^3/uL (within 28 days prior to registration) * Total bilirubin ≤ institutional upper limit of normal (ULN) unless history of Gilbert's disease (within 28 days prior to registration) * Participants with history of Gilbert's disease must have total bilirubin ≤ 5 x institutional ULN * Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ≤ 3 x institutional ULN (within 28 days prior to registration) * Participants must have a creatinine ≤ the institutional (I)ULN OR measured OR calculated creatinine clearance ≥ 40 mL/min using the following Cockcroft-Gault Formula. This specimen must have been drawn and processed within 3 days prior to registration * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class II or better * Participants with a history of human immunodeficiency virus (HIV)-infection must be on effective anti-retroviral therapy at registration and have undetectable viral load test on the most recent test results obtained within 6 months prior to registration * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Participants with a history of hepatitis C virus (HCV) infection must have been treated and cured (defined as undetectable HCV viral load) * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen * Participants must not be pregnant or nursing (nursing includes breast milk fed to an infant by any means, including from the breast, milk expressed by hand, or pumped). Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen * Participants must be offered the opportunity to participate in specimen banking * Participants who can complete the PRO-CTCAE questionnaire in English or Spanish will be offered the opportunity to participate in the optional patient-reported outcome study * NOTE: As a part of the Oncology Patient Enrollment Network (OPEN) registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines * For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and central institutional review board (CIRB) regulations

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, PROCEDURE: Cystoscopy, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Pembrolizumab, RADIATION: Photon Beam Radiation Therapy, PROCEDURE: Positron Emission Tomography, OTHER: Questionnaire Administration, PROCEDURE: Transurethral Resection of Bladder Tumor

Conditions:

Muscle Invasive Bladder Urothelial Carcinoma, Stage II Bladder Cancer AJCC v8, Stage IIIA Bladder Cancer AJCC v8

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

IRB

Number:

System ID: NCT07061964

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