Testing the Addition of the Drug BMX-001, a Radioprotector, or a Placebo to the Usual Chemoradiation Therapy for Patients With Head and Neck Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must be planned to receive radiation and concurrent cisplatin chemotherapy as definitive therapy. Patients planned to receive concurrent cisplatin and radiation therapy in the adjuvant setting are not eligible. * At least two subsites (buccal mucosa, lips, retromolar trigone, floor of mouth, oral tongue, tonsil, soft palate, or hard palate) must have at least 1cc or 1% of the subsite volume receiving \>= 50 Gy. In cases of uncertainty, the enrolling clinician can ensure coverage by inspecting the 50 Gy isodose line and using the table describing the anatomic boundaries of the individual subsites contained within the extended cavity contour. The two or more subsites receiving \>= 50 Gy must be documented by the enrolling physician. * Pathologically confirmed (histologically or cytologically) squamous cell carcinoma of the oropharynx, larynx, hypopharynx, nasopharynx, or oral cavity. * P16 and/or human papillomavirus (HPV) status (via polymerase chain reaction \[PCR\] or in situ hybridization \[ISH\]) must be documented for patients with oropharynx cancer. * No patients with T0/Tx/unknown primary disease. * No definitive clinical or radiologic evidence of metastatic (M1) disease related to current diagnosis. * Able to receive intensity-modulated radiation therapy (IMRT) delivered as daily fractions of 2.0 Gy once per weekday with a cumulative radiation dose of 70 Gy. * Age \>= 18. * Zubrod performance status of 0-2. * Potassium ≥ institutional lower limit of normal (LLN) and magnesium ≥ institutional LLN. Oral or intravenous (IV) replacement therapy of potassium or magnesium is permitted if parameters can be met after repletion. * Absolute neutrophil count (ANC) \>= 1,500 cells/mm\^3. * Platelets \>= 100,000 cells/mm\^3. * Hemoglobin \>= 9.0 g/dl (Note: The use of transfusion or other intervention to achieve hemoglobin \[Hgb\] \>= 10.0 g/dl is acceptable). * Adequate renal function defined as creatinine clearance (CrCL) \> 50 mL/min by the Cockcroft-Gault formula. * Total bilirubin =\< 2 x institutional upper limit of normal (ULN) (not applicable to patients with known Gilbert's syndrome). * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 3 x institutional ULN. * No prior radiotherapy that would result in overlap of radiation treatment fields with planned treatment for study cancer, e.g., breast cancer with irradiation of the supraclavicular fossa/level 4 neck. * No concurrent treatment with nitrates or other drugs that may, in the judgment of the treating investigator, create a risk for a precipitous decrease in blood pressure. * No prior history of gross total excision of both primary and nodal disease; this includes tonsillectomy, local excision of primary site, and nodal excision that removes all clinically and radiographically evident disease. In other words, to participate in this protocol, the patient must have clinically or radiographically evident gross disease for which disease response can be assessed. * No current treatment of adjuvant post-operative (op) chemoradiation. * No systemic treatment with inducers or strong inhibitors of cytochrome P450 =\< 4 days before registration. Note: Patients undergoing steroid treatment as a component of the anti-emetic regimen for cisplatin are eligible for the study. Treatment with the antifungal medications, nystatin, fluconazole , miconazole and clotrimazole are allowed. * No prior induction chemotherapy treatment. * No prior unrelated malignancy requiring current active treatment with the exception of cervical carcinoma in situ, basal cell skin carcinoma, resected T1-2N0M0 differentiated thyroid cancers, Ta bladder cancers, or low risk prostate cancer. * No clinically significant hearing impairment that precludes cisplatin, as per physician assessment. * No serious cardiovascular disease or cerebrovascular disease in the last 6 months prior to study enrollment; defined as a cerebrovascular accident, myocardial infarction, unstable angina, serious cardiac arrhythmia uncontrolled by medication or with the potential to interfere with protocol treatment, or current New York Heart Association (NYHA) grade II or greater congestive heart failure (CHF), or admission within last 6 months for CHF exacerbation; (Note: 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). * No valvular heart disease. * No significant vascular disease (e.g., aortic aneurysm requiring surgical repair or recent arterial thrombosis) within 6 months prior to enrollment. * No history or evidence upon physical/neurological examination of central nervous system disease (e.g., seizures) unrelated to cancer unless adequately controlled by medication. * No acute bacterial, viral, or fungal infection requiring intravenous antimicrobials within 7 days of enrollment. * No history of chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy within 30 days of registration. * No known personal or family history of long QT Syndrome; no marked baseline prolongation of QT/corrected QT (QTc) interval (i.e., ≥ 2 electrocardiograms \[EKGs\] in prior 3 months of a QTc interval \> 450 milliseconds (ms) for males and \> 470 ms for females using the specific/usual choice by clinical center for correction factor. * Persistent grade 3-4 (CTCAE version 5.0) electrolyte abnormalities must be reversible to ≤ grade 1 with supplementation. * No poorly controlled hypertension (systolic blood pressure \[SBP\] \> 160 and/or diastolic blood pressure \[DBP\] \> 95) over 2 repeated measures within 30 days prior to registration. * No grade \>= 2 oral mucositis per CTCAE version 5.0. * No grade \>= 2 hypotension per CTCAE v. 5.0. * No medical necessity for anti-arrhythmics with significant risk of QTc prolongation such as class I and class III anti-arrhythmics. These include but are not limited to amiodarone, quinidine, dofetilide, sotalol, flecainide, and lidocaine. * No medical necessity for medications listed as prohibited. * For standard management of oral mucositis, clinicians may consult the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) Clinical Practice Guidelines for the Management of Mucositis Secondary to Cancer Therapy. The only intervention against mucositis that is supported by level I evidence is low-level laser therapy (LLLT). Honey is rated at level II and benzydamine, which isn't available in the United States (US), is rated at level III. There are no other positively rated interventions. * LLLT is prohibited in this study as its availability remains limited, it is not Food and Drug Administration (FDA) approved in the US, and it is considered investigational in many circumstances requiring enrollment in a dedicated protocol who requirements could conflict with this one. Therefore, institutions that use LLLT should only enroll patients who would not be eligible for (or do not want) that intervention. Honey is not on the list of prohibited medications for this study. Given the MASCC recommendation, benzydamine is allowed, although there is lack of availability in the United States of America (USA). The other listed prohibited medications are not recommended by MASCC and some are potentially harmful, such as glutamine, which is associated with mortality in patients receiving stem cell transplant. * No history of allergic reaction to the study agent(s), compounds of similar chemical or biologic composition to the study agent (s) (or any of its excipients). * Childbearing potential is defined as any person who has experienced menarche and who has not undergone surgical sterilization (hysterectomy or bilateral oophorectomy) or who is not postmenopausal.

Conditions & Interventions

Interventions:

OTHER: Best Practice, PROCEDURE: Biospecimen Collection, DRUG: Cisplatin, PROCEDURE: Computed Tomography, RADIATION: Image Guided Radiation Therapy, RADIATION: Intensity-Modulated Radiation Therapy, PROCEDURE: Magnetic Resonance Imaging, DRUG: MnSOD Mimetic BMX-001, DRUG: Placebo Administration, OTHER: Questionnaire Administration

Conditions:

Clinical Stage I HPV-Mediated (p16-Positive) Oropharyngeal Carcinoma AJCC v8, Clinical Stage II HPV-Mediated (p16-Positive) Oropharyngeal Carcinoma AJCC v8, Clinical Stage III HPV-Mediated (p16-Positive) Oropharyngeal Carcinoma AJCC v8, Head and Neck Squamous Cell Carcinoma, Hypopharyngeal Squamous Cell Carcinoma, Laryngeal Squamous Cell Carcinoma, Nasopharyngeal Squamous Cell Carcinoma, Oral Cavity Squamous Cell Carcinoma, Oropharyngeal Squamous Cell Carcinoma, Stage 0 Head and Neck Cutaneous Squamous Cell Carcinoma AJCC v8, Stage 0 Hypopharyngeal Carcinoma AJCC v8, Stage 0 Nasopharyngeal Carcinoma AJCC v8, Stage 0 Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage I Head and Neck Cutaneous Squamous Cell Carcinoma AJCC v8, Stage I Hypopharyngeal Carcinoma AJCC v8, Stage I Laryngeal Cancer AJCC v8, Stage I Lip and Oral Cavity Cancer AJCC v8, Stage I Nasopharyngeal Carcinoma AJCC v8, Stage I Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage II Head and Neck Cutaneous Squamous Cell Carcinoma AJCC v8, Stage II Hypopharyngeal

Stage I Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage II Head and Neck Cutaneous Squamous Cell Carcinoma AJCC v8, Stage II Hypopharyngeal Carcinoma AJCC v8, Stage II Laryngeal Cancer AJCC v8, Stage II Lip and Oral Cavity Cancer AJCC v8, Stage II Nasopharyngeal Carcinoma AJCC v8, Stage II Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage III Head and Neck Cutaneous Squamous Cell Carcinoma AJCC v8, Stage III Hypopharyngeal Carcinoma AJCC v8, Stage III Laryngeal Cancer AJCC v8, Stage III Lip and Oral Cavity Cancer AJCC v8, Stage III Nasopharyngeal Carcinoma AJCC v8, Stage III Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage IVA Hypopharyngeal Carcinoma AJCC v8, Stage IVA Laryngeal Cancer AJCC v8, Stage IVA Lip and Oral Cavity Cancer AJCC v8, Stage IVA Nasopharyngeal Carcinoma AJCC v8, Stage IVA Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage IVB Hypopharyngeal Carcinoma AJCC v8, Stage IVB Laryngeal Cancer AJCC v8, Stage IVB Lip and Oral Cavity Cancer AJCC v8, Stage IVB Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stomatitis

More Information

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