Study to Evaluate the Feasibility of Twice Daily Use of Topical Azelaic Acid in Breast Cancer Patients Undergoing Radiation

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Age ≥ 18 years * Self-reports as Black, Asian, Hispanic/Latin, ethnically originating from the Mediterranean rim or Pacific rim, or she/he tans easily in the sun * Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2 (Appendix 1, Section 18) * Attestation by the patient that she/he is not pregnant, lactating, or planning to become pregnant during the study period * Histologic confirmation of breast malignancy (with TNM staging) If the patient did not receive adjuvant chemotherapy, adjuvant radiation must start within 180 days of lumpectomy or mastectomy. If the patient received adjuvant chemotherapy, adjuvant radiation should start within 60 days of the last dose of chemotherapy * Treatment plan includes one of the following: * Conventionally fractionated whole breast radiation (45-50 Gray in 25 fractions) * Moderately hypofractionated whole breast radiation (42.56 Gray in 16 fractions or 40 Gray in 15 fractions) * Conventionally fractionated chest wall radiation (45-50 Gray in 25 fractions) * Treatment of the regional lymph nodes, a tumor bed boost (4-8 fractions), and use of tissue-equivalent bolus on the chest wall may be included at the discretion of the treating physician. * Radiation will be photon-based. Note: If the patient receives a boost, photons and/or electrons may be used at the discretion of the treating physician.

Exclusion Criteria:

* Prior radiotherapy to any portion of the planned treatment site * Current inflammatory breast cancer or gross dermal involvement at initiation of radiotherapy * Concomitant immunotherapy or cytotoxic chemotherapy. Concomitant HER2 directed therapy or concomitant endocrine therapy is allowed * Active rash or dermatitis within the treatment field, or a history of any rash or dermatologic condition within the treatment field * Co-existing medical conditions resulting in life expectancy \< 1 years * Active collagen vascular diseases (ie lupus erythematosus, scleroderma, dermatomyositis) * History of organ transplant or bone marrow transplant * History of hypersensitivity or allergic reaction to any ingredients in the topical azelaic acid formulation * Has used within 1 month prior to baseline: * topical retinoids to the breast * oral retinoids * systemic (oral or injectable) antibiotics known to have an impact on the severity of skin rash or sun-sensitivity (eg, containing tetracycline and its derivatives, erythromycin and its derivatives, sulfamethoxazole, or trimethoprim) * systemic corticosteroids or immunosuppressive drugs * Has used on treated breast within 2 weeks prior to baseline: * topical corticosteroids * topical antibiotics * topical medications for skin rash (eg, metronidazole, azelaic acid) * Radiation therapy will be proton therapy or carbon therapy * External beam partial breast irradiation, brachytherapy partial breast irradiation, or intraoperative radiation are included in the treatment plan Medical, psychological, or social condition that, in the opinion of the investigator, may increase the patient's risk or limit the patient's adherence with study requirements

Conditions & Interventions

Interventions:
DRUG: Azelaic Acid
Conditions:
Breast Cancer

More Information

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Principal Investigator:
Phase: PHASE1
IRB
Number:
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