M-PART in Head and Neck Cancer Patients Treated With KeraStat Cream for Acute Radiation Dermatitis

NCT06441266

Status	RECRUITING
Phase	Not Applicable
Sponsor	Wake Forest University Health Sciences
Enrollment	16 participants

Plain Language Summary

This study tests KeraStat Cream — a topical skin treatment — for helping prevent or heal radiation dermatitis, the painful, inflamed skin reaction that commonly occurs during radiation therapy for head and neck cancer. The M-PART method combines nursing assessments with patient self-reporting for comprehensive monitoring.

You may be eligible if...
- You have been diagnosed with head and neck cancer (including cancers of the mouth, throat, voice box, or sinuses)
- You are scheduled to receive standard radiation therapy (at least 60 Gy total dose) to the head and neck area

You may NOT be eligible if...
- You are receiving a non-standard radiation schedule
- You have a skin condition that would interfere with evaluation of radiation dermatitis
- You are unable to provide consent or attend required study visits

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (5)

- \- Histological or cytological diagnosis of head and neck cancer (of any part of the oral cavity, pharynx, larynx, or sinuses) planned to receive conventionally fractionated radiation therapy (RT) targeting the head and neck to a total prescribed dose of at least 50 Gy. The 50 Gy radiation therapy target must include at least a part of the unilateral and/or bilateral lymph node regions of the head/neck. Planned prescribed dose will be reviewed and approved by the study principal investigator.
- NOTE: Patients without a clear pathologic diagnosis of invasive disease (i.e., biopsy showing at least carcinoma in situ) but with clinically diagnosed head and neck cancer planned for treatment as above are also eligible.
- Age e 18 years at the time of enrollment.
- Able and willing to complete electronic toxicity and quality of life assessments in the MyCap application using their personal mobile device.
- Ability to understand and the willingness to sign an IRB-approved informed consent document (either directly or via a legally authorized representative) in English.

Exclusion (7)

- Early stage (Stage I-II) squamous cell carcinoma of the glottic larynx planned for treatment with limited field radiation therapy alone. These participants are excluded since they are expected to receive a more limited exposure to radiation therapy.
- Patients planned for treatment to the primary site alone without regional lymph node targeting.
- Previous radiation therapy to the area in the head and neck to be treated with radiation therapy.
- Active use of topical corticosteroids in the irradiation area at the time of enrollment. Note that it is acceptable to use topical corticosteroids if study participants develop moist desquamation during radiation therapy.
- History of scleroderma or active lupus requiring systemic medication at the time of enrollment

... and 2 more (see full listing online)

Locations (1 total)

Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, North Carolina, United States