NRG Oncology Trial to Evaluate Less-Intensive Therapy for Patients with Oropharyngeal Cancer at Low Risk for Cancer Recurrence

Philadelphia, PA—Clinical trial results published by NRG Oncology and Groupe d’Oncologie Radiothérapie Tête Et Cou have established the current standard-of-care treatment for patients with stage III or IV oropharyngeal cancer (OPC) as radiotherapy (70 Gy) delivered concurrently with platinum-based chemotherapy. However, this treatment regimen is often associated with debilitating short- and long-term side effects. For patients with human papillomavirus (HPV)-positive OPC whose prognosis is excellent, with a high probability of long-term survival, the chemoradiotherapy-related side effects are of significant concern.

Patients who develop HPV-associated OPC are more likely to be younger and healthier, with a briefer history of smoking. Because these patients most often have significantly improved survival subsequent to undergoing therapy at a young age, long-term treatment side effects present compelling quality-of-life (QOL) issues. The NRG-HN002 phase II clinical trial activated on October 27 seeks to define new, less-intensive treatment options for this patient population.

“The emerging low-risk oropharyngeal cancer classification offers an opportunity to develop appropriate therapeutic paradigms for the recently identified and distinct subtype of HPV-positive disease,” says trial Principal Investigator Sue S. Yom, M.D., Ph.D., an associate professor in the departments of radiation oncology and otolaryngology-head and neck surgery at the University of California, San Francisco. “The NRG-HN002 trial will evaluate two new treatment options—one of chemoradiotherapy and the other of radiotherapy alone. Our goal is to evaluate whether these modestly less-intensive therapies result in the same excellent outcomes and low treatment-associated toxicity observed in the RTOG 0129 and RTOG 0522 trials of oropharyngeal cancer.”

In previous studies, p16 staining of tumor specimens was established by the RTOG as a selection mechanism to identify HPV-positive oropharyngeal cancers. For this study participants who have been determined to have HPV-positive OPC, reflect a minimal smoking history, and meet the other eligibility criteria will be randomized into one of two treatment arms. Participants in Arm 1 will undergo radiotherapy at a modestly reduced dose and concurrent chemotherapy (60 Gy/30 fractions/6 weeks, with weekly cisplatin at 40/mg/m²). Participants in Arm 2 will undergo radiotherapy at an accelerated schedule of modestly reduced dose (60 Gy/30 fractions/5 weeks). Comparison of the two treatment strategies will provide insight as to whether systemic radiosensitization provides any advantage over an altered-fractionation radiotherapy-alone approach.

Patient-reported outcomes and QOL data will be collected to evaluate the potential reduction in side effects from the patient’s perspective. These findings will identify the least toxic arm with respect to achieving a better swallowing QOL outcome while maintaining a progression-free survival rate of at least 85% at 2 years post treatment. The investigators hypothesize that—for the two approaches being tested—swallowing-related QOL will be superior in Arm 2 (radiotherapy alone) compared with Arm 1 (chemoradiotherapy) at 1 year post treatment. These trial data will inform decisions regarding which of the two treatment arms may proceed to a phase III randomized trial for evaluation with other treatment de-intensification approaches.

“Reduced-total-dose radiotherapy is expected to diminish both acute and long-term toxicity and, if similar survival outcomes are preserved, these efforts will redefine rapidly the landscape of oropharyngeal cancer clinical investigations and future treatment,” says Yom.
NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research strengths of the National Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group and the Gynecologic Oncology Group. The research organization seeks to carry clinical trials with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types. NRG Oncology’s extensive research organization is comprised of multidisciplinary investigators including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians and encompasses more than 1300 research sites located worldwide with predominance in North America. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.