

ECOG-ACRIN EA3163 Phase II randomized trial of neo-adjuvant chemotherapy followed by surgery and post-operative radiation versus surgery and post-operative radiation for organ preservation of T3 and T4a nasal and paranasal sinus squamous cell carcinoma (NPNSCC)

Nabil F Saba; Yael Flamand, Derrick Lin, Christine Chung, Rathan Subramanian, Mark McDonald, Stella Flampouri, Saad Khan, Fenghai Duan, Bapsi Chakravarthy, Barbara Burtress

Background: Nasal and paranasal sinus squamous cell carcinoma (NPNSCC) account for 3% of all malignancies of the head and neck with squamous cell carcinoma being the most predominant histologic type. The standard of care for T3 and T4a NPNSCC has been surgical resection with possible need to sacrifice structures including the orbit and base of skull. little or no advances have been made in the treatment of this disease and the 2-year local disease control does not exceed 50-60%.

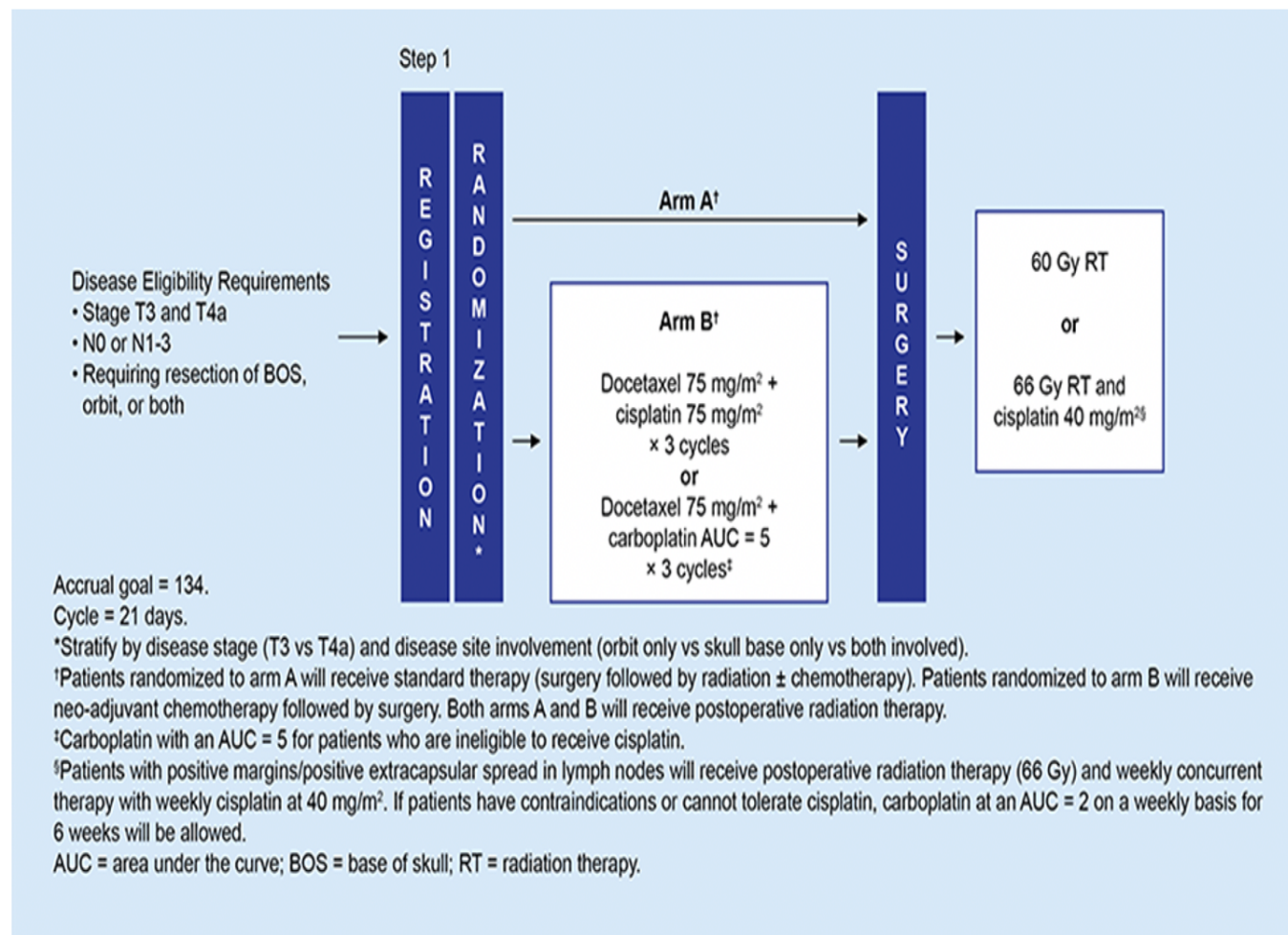
ECOG-ACRIN EA3163 raises the question of whether a better cytoreductive pre-operative approach would provide improved structure preservation and overall survival with a potential for better locoregional control for patients with resectable T3 or T4a NPNSCC.

Single arm, single institution studies suggested that systemic therapy in the preoperative setting could make a difference in locoregional control as well as structure preservation. These series have however fallen short of establishing neo-adjuvant therapy as an effective approach that would have clinical benefit to patients with resectable NPNSCC. EA3163 is set to provide a definitive answer to this crucial question.

Objectives and patient selection:

The primary objectives include evaluating

- 1- the structure preservation rate for patients with locally advanced resectable NPNSCC with or without neoadjuvant therapy; (all patients will undergo surgical resection and postoperative standard care)
- 2- the overall survival (OS) for the same patient population. EA3163 is currently accruing at ECOG-ACRIN and CTSU sites.



This study is being conducted by the ECOG-ACRIN Cancer Research Group (Peter J. O'Dwyer, MD and Mitchell D. Schnall, MD, PhD, Group Co-Chairs) and supported by the National Cancer Institute of the National Institutes of Health under award numbers U10CA180820, U10CA180794, UG1CA233180, UG1CA233247, UG1CA233270, UG1CA233302, UG1CA233337. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.