Patient Population
See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years, ECOG PS 0-1, adequate lab values
- Must have a general physical condition compatible with the proposed chemotherapy and surgery
- Must have stage T3 or T4a (or select T4b), histologically -confirmed NPNSCC requiring orbital or skull base resection (see protocol for details); must have measurable disease per protocol
- Must be deemed surgically resectable by the surgical teams at each institution and must have a determination of degree of anticipated structure preservation of orbit and skull base prior to randomization, per protocol
- May not be receiving investigational agents at time of randomization, while on study, or during 4 weeks preceding randomization
- No history of allergic reactions attributed to compounds of similar chemical/biologic composition to docetaxel and/or both platinum-based chemotherapy agents (must be able to receive 1 chemo regimen)
- No patients with evidence of distant metastases or leptomeningeal disease
- No previous irradiation for head and neck tumor, skull base, or brain tumors
- No patients with uncontrolled intercurrent illness which in the opinion of the investigator will interfere with the ability to undergo therapy
- No patients with a history of a different malignancy, unless the disease has not progressed for ≥ 2 years; patients with a prior history of squamous cell/basal carcinoma of the skin or in situ cervical cancer must have been curatively treated
- Must not have current peripheral neuropathy > grade 2 at time of randomization
- No co-existing condition what would preclude full compliance with the study
- No prior history of severe hypersensitivity reaction to Docetaxel/other drugs formulated with polysorbate 80

Treatment Plan
See Section 5.0 for Complete Treatment Details

Arm A:
- Imaging scans will be obtained within 2 weeks prior to randomization and within 4 weeks prior to surgical resection
- Following surgery, patients will need to receive post-operative radiation to 60 Gy to the primary tumor and neck nodes; patients with positive margins/extracapsular spread in lymph nodes will receive 66 Gy with weekly cisplatin at 40 mg/m² x 6 weeks concurrent with radiation
  ◊ Carboplatin AUC= 2 x 6 weeks is permitted

Arm B:
- Imaging scans will be obtained within 2 weeks prior to randomization and within 4 weeks prior to initiation of chemotherapy
- Neoadjuvant chemotherapy with 3 cycles of docetaxel 75 mg/m² with cisplatin at 75 mg/m² (or carboplatin AUC=5); administered every 21 days
- Following completion of chemotherapy, patients will proceed to surgical resection no later than 6 weeks following last dose
- Imaging scans will be obtained within 3 weeks post completion of chemotherapy
- Following surgery, patients will need to receive post-operative radiation to 60 Gy to the primary tumor and neck nodes; patients with positive margins/extracapsular spread in lymph nodes will receive 66 Gy with weekly cisplatin at 40 mg/m² x 6 weeks concurrent with radiation
  ◊ Carboplatin AUC= 2 x 6 weeks is permitted

Notes:
- See protocol for hydration, antiemetics, surgical guidelines, and radiation details
- A +/− 2 day window is allowed for chemotherapy administration; chemotherapy may be given before or after radiation therapy

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

Please Enroll Your Eligible Patients!
1. Study by disease stage (T1b vs. T4a), and disease site involvement (distant only vs. skull base only vs. both involved).

Actual Goal: 82
t cycle = 21 days

Schema