

Clinical Trial in the Spotlight

SEPTEMBER 2009

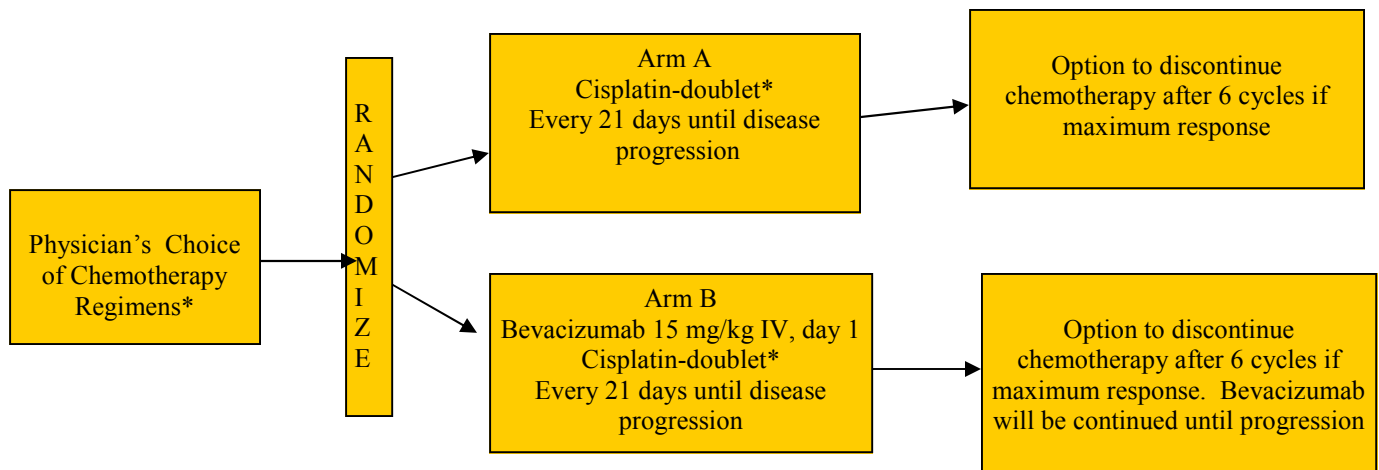
A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer

This randomized Phase III trial is investigating the addition of bevacizumab to standard cisplatin-based chemotherapy in patients with squamous cell carcinoma of the head and neck (SCCHN). Bevacizumab is a humanized monoclonal antibody that targets and inhibits the function of vascular endothelial growth factor (VEGF), a natural protein that stimulates new blood vessel formation. This study hypothesizes that the addition of bevacizumab to standard cisplatin-based chemotherapy will result in survival benefit in patients with recurrent or metastatic SCCHN. Eligible patients will be randomized to one of two treatment arms: chemotherapy and bevacizumab or chemotherapy alone.

Eligibility criteria include:

- Histologically or cytologically confirmed Squamous Cell Cancer of the Head and Neck (SCHNN) from any primary site
- Age > 18 years of age.
- No prior bevacizumab
- ECOG performance status of 0-1
- No known brain metastases
- No prior chemotherapy or biologic/ molecular targeted therapy for recurrent or metastatic SCHNN
- More that 4 weeks since surgery or open biopsy
- No unstable angina or myocardial infarction within the past 6 months

TRIAL SCHEMA



Cycle = 21 days

All doses will be based on patient's actual weight

*Chemotherapy regimen choices:

- 1) Docetaxel 75mg/m² IV on day 1, followed by Cisplatin 75mg/m² IV on day 1, every 21 days
- 2) Cisplatin 100mg/m² IV on day 1, 5-FU 1000mg/m²/day continuous infusion x 4 day, every 21 days

To learn more about this trial and other clinical trials offered at Roger Williams Medical Center

Please visit our website at:

http://www.rwmc.org/cancer_care.htm