

## Low dose Docetaxel, Carboplatin and Capecitabine in the treatment of recurrent and/or metastatic Head and Neck Cancer (HNC): Results of a Pilot Phase II study

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### Abstract

**Rationale:** Platinum-based treatment is the standard of care for patients having Head and Neck Cancer (HNC). Many combination regimens were investigated adding Taxane or 5-FU to Cisplatin or Carboplatin resulting in response rates of 30% to 40%. Combination of Cetuximab these regimens produced interesting results.

**Objective:** The primary objective is to assess the efficacy and toxicity of the combination of Docetaxel, Carboplatin and Capecitabine in the treatment of HNC. Results of this pilot phase II trial will serve as a feasibility study in order to assess the possibility of addition of Cetuximab to this combination.

**Patients and Methods:** Between January 2002 and August 2004, patients with recurrent or metastatic HNC received the combination of: Docetaxel 25 mg/m<sup>2</sup> on days 1 & 8, Carboplatin AUC 2 on days 1 & 8 and Capecitabine 1350 mg/m<sup>2</sup> per day for two consecutive weeks, repeated every 21 days.

**Results:** Twenty patients have been enrolled. There were 20 % of complete response (4 pts), 30 % (6 pts) of partial response resulting in an overall response rate of 50 % (IC 95%: 27.20 – 72.80 %). The median overall survival was 5.2 months. The major hematological toxicities were Grade 2 and 3 anemia in 12 patients (60 %) and 2 patients (10 %) respectively and febrile neutropenia in 2 patients (10 %). The non-hematological toxicities were mainly nausea, vomiting and stomatitis.

**Conclusion:** This combination showed good results with acceptable toxicity profile. It warrants to be studied in addition to Cetuximab in metastatic and recurrent Head and Neck Cancer.