500 mg/m^2 every 2 weeks, weekly cetuximab (400 mg/m^2 on day 1 then 250 mg/m^2 weekly), and combination with weekly cetuximab and docetaxel (35 mg/m^2 on day 1, 8 and 15 every 28 days) in 44%, 40% and 15% of pts.
ORR was 15%. Partial response, stable disease and progression rates were respectively PR = 15%, SD = 30% and PD = 55%. A toxic death occurred in one case related to an anaphylactic shock.
The median PFS was 9 weeks for all patients. The median PFS of patients treated with weekly cetuximab and cetuximab every 2 weeks was respectively: 12 weeks and 8 weeks. Median PFS of pts treated with cetuximab and taxotere combination was 6 weeks.
Conclusion: This monocentric retrospective study confirmed that cetuximab alone may confer clinical benefit as second-line or third-line treatment for pts with R/M SCCHN, with a 45% disease control rate, but median PFS remained shorter than three months.

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Impact of Induction Chemotherapy on Local Control for Locally Advanced Nasopharyngeal Cancer

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Background: Concurrent chemoradiotherapy (CRT), with or without adjuvant chemotherapy, is a current standard of care for locally advanced nasopharyngeal carcinoma (NPC). However, prognosis of patients (pts) with stage IV or N2-N3 remains poor. Recently, induction chemotherapy (IC) followed by CRT demonstrated promising results in a randomized phase II trial (Hui EP et.al, JCO 2009). We retrospectively conducted a nonrandomized comparison between CRT alone and IC followed by CRT in NPC pts with stage IVA-IVB or N2−N3.
Method: Between Apr.1996 and Sep.2009, 54 consecutive pts were selected for this study: 32 were treated with CRT alone and 21 with IC followed by CRT. IC consisted of 1-hour infusion of docetaxel at 60 to 70 mg/m^2, 2-hour infusions of cisplatin at 60 to 70 mg/m^2/day on day 1 and of S-1 twice daily on days 1−14 at 60−80 mg/m^2/day, repeated every 3 or 4 weeks with a maximum of 3 cycles allowed (Tahara M et.al, Ann Oncol 2011). After completion of IC, pts received 66−70 Gy of radiotherapy concurrent with cisplatin. CRT alone consisted of 66−70 Gy of radiotherapy with platinum-based chemotherapy with or without adjuvant chemotherapy.
Results: No differences in sex, PS and median age in both groups were observed, but patients in the IC group had a more advanced stage (stage IVA-IVB: 76% vs. 63%, N2−3: 90% vs. 78%). During IC, the most common grade 3 or 4 hematological toxicities were neutropenia (76%) and febrile neutropenia (10%) while the most common grade 2 or 3 non-hematological toxicities were anorexia (42%), nausea (42%) and diarrhea (19%). During CRT, hematological and non-hematological toxicities were not increased in the IC group. After completion of IC, complete response was observed in one pt and partial response in 20 pts according to RECIST criteria. Median followed-up period was 29 months in the IC group and 42 months in the CRT group. 2-year progression free survival and overall survival were respectively 76% and 95% in the IC group and 71% and 83% in the CRT group. Recurrences of primary site were observed in one pt (5%) in the IC group and 8 pts (25%) in the CRT group.
Conclusion: IC was well tolerated and did not compromise sequent CRT. IC followed by CRT demonstrated better local control compared with CRT and further investigation is warranted.

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A Phase II Analysis of Paclitaxel and Capecitabine in the Treatment of Recurrent or Disseminated, Squamous Cell Carcinoma of the Head and Neck Region − Results From an Extended Phase 2 Study

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Background: This study presents the results of an extended phase II study originally published in 2007 (HEAD & NECK jan. 2007), regarding the antitumour activity and toxicity of a non-platinum containing regime with paclitaxel and capecitabine for the treatment of recurrent or disseminated squamous cell carcinoma of the head and neck region. 50 patients were included in the original study and as the results were promising with respect to response (42%), overall survival (8 month's) and toxicity (very low), we decided to accrue another 100 patients in order to provide a more robust estimate of response and survival with this regime.
Materials and Methods: A total 183 patients with recurrent or disseminated squamous cell carcinoma were included in the study. There were 37 women and 146 men. Mean age was 56 years. Performance (WHO) was as follows: WHO 0: 31, WHO 1: 107 and WHO 2: 45 patients. The treatment consisted of paclitaxel 175 mg/m^2, once every third week and capecitabine 825 mg/m^2 p.o. b.i.d for 2 weeks.
Results: The overall response rate (CR and PR) according to the WHO criteria's was: 32.6%. (CR: 6%; PR: 26.6%; NC: 36.4%; PD: 20.7% NE: 8.2% and Not Known: 2.1%.) The mean survival time was 254 days or 8.5 month's for the entire population, but for patients in performance 0 and 1 only the mean survival time was 313 days or 10.4 month's. Toxicity was very moderate. Only 9% of 1131 delivered treatments had to be given in reduced dose. Apart from hairloss (50% had total hairloss) toxicity was low and grade 3 and 4 toxicity were uncommon. Two toxic deaths were registered though.
Conclusions: The response rate and overall survival for this low toxic regime are promising and comparable to the much recommended regime with Cisplatinum, 5Fu and Cetuximab (Vermorken regime).

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Pilot Study of Target Therapy With EGFR Antibody (Nimotuzumab) in Patients With Unresectable Head and Neck Cancer

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Background: Nimotuzumab, a humanized anti-EGFR monoclonal antibody, has demonstrated well tolerate anti-cancer efficacy. Therefore, we designed this study to explore the efficacy of the combination of biological target therapy (utilize Nimotuzumab) and chemotherapy with unresectable neck and head carcinomas.
Material and Methods: 71 patients (54 men and 17 women, age 30−83 years, mean 60) were enrolled in this study. All patients had locally advanced oral-maxillofacial and head and neck tumours (no indication for surgery or radiotherapy) confirmed by histology and radiology, with indication for biochemotherapy. The chemotherapy regimen given was cisplatin 75 mg/m^2 day 1, paclitaxel 75 mg/m^2 day 1, fluorouracil 750 mg/m^2 days 1−5, and Nimotuzumab 200 mg/m^2 weekly.
Results: Patients completed 2−4 cycles of chemotherapy (mean 2.2). Nimotuzumab was given 2−8 times (mean 4.3). The prognosis was as follows: complete response in 4 patients, partial response in 39, stable disease in 18, and progressive disease in 3. 7 patients could not be evaluated. The total effective rate, calculated as complete plus partial responses, was 61%. 29 patients had surgery after biochemotherapy. No serious adverse reactions were noted during the course of the treatment, only one case of slight erythra infection.
Conclusions: Nimotuzumab was equally effective in the increase of chemosensitivity and good tolerability profiles.

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COX-2 Inhibitor and Gefitinib in Recurrent And/or Metastatic Head & Neck Cancer

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Background: Metastatic and/or Recurrent Head & Neck Cancer patients following definitive therapy in the form of multi modality therapy, has dismal prognosis and options are extremely limited with only the combination of Cetuximab and Cisplatinum improving quality of life and overall survival.
Epidermal growth factor (EGFR) plays a role in tumorigenesis, stimulating cell proliferation, inhibiting apoptosis and promoting angiogenesis and metastasis. EGFR is over expressed in majority of Head & Neck cancer patients and is associated with poor prognosis and outcome.
Cylooxygenase-2 (COX-2) is also over expressed in Head & Neck cancer with poor outcome. Interaction of EGFR and COX-2 suggest that EGFR activates COX-2 in Head & Neck cancer.
Materials and Methods: Single institute study was done to find out safety and efficacy of combining Gefitinib and COX-2 inhibitor Eterocoxib. The study was done in 2 phases. Phase 1 was for dose finding and Phase 2 − a randomized pilot study comparing Gefitinib + Eterocoxib vs Methotrexate