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Phase II study of weekly chemotherapy with paclitaxel and gemcitabine as second-line treatment for advanced non-small cell lung cancer after treatment with platinum-based chemotherapy

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Background: Second-line chemotherapy has become almost routine in non-small cell lung cancer (NSCLC) patients (pts) with good performance status (PS). The availability of the new pharmacological agents opens up new possibilities for their use in pts who have retained a good PS following relapse or progression after first-line chemotherapy. Paclitaxel (PTX) and Gemcitabine (GEM) are among the most active new agents in NSCLC and are worth considering for second-line chemotherapy. In phase II study, we evaluated the tolerability and activity of the combination of weekly PTX and GEM in second-line treatment of NSCLC.
Material and Methods: PTX (100 mg/m^2) and GEM (1000 mg/m^2) were administered to NSCLC patients with previous treatment of platinum-based chemotherapy on days 1 and 8 every 3 weeks. A total of 40 pts (M/F, 27/13 pts; median age 59.3 years [33−75]; PS 0/1/2, 7/27/6 pts) were enrolled.
Results: The mean number of cycles administered per patient was 4, and number of cycles ranged from one to twelve. The final efficacy was PR in 13, NC in 26 and PD in 1 for a response rate of 32.5% (95% CI: 18−47%). The median survival time was 41.7 weeks (95% CI: 28.5−54.7 weeks). The median time to progressive disease was 19 weeks. Hematologic toxicities observed included grade 3 or 4 neutropenia in 60%, grade 3 or 4 anemia in 15%, and grade 3 or 4 thrombocytepenia in 12.5%. Non-hematologic toxicities were mild except grade 3 pneumonitis in 1 pt. There were no toxic deaths.
Conclusion: The combination of weekly PTX and GEM is a feasible, well-tolerated, and active scheme for second-line treatment of advanced NSCLC.

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Does the use of erlotinib for the treatment of relapsed stage IIIB/IV NSCLC patients improve quality-adjusted survival compared with docetaxel?

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Background: The main outcome of interest in the treatment of NSCLC is overall survival (OS). However, quality of life (QoL) can also be a significant consideration when selecting the most appropriate treatment strategy. The Quality Adjusted Life Year (QALY) is a measure of the effectiveness of a medical intervention that is increasingly used, especially within the context of pharmaceutical cost/benefit analysis. The QALY is a generic measure of health gain that captures both the quantity and the quality of life experienced by the patient. The following analysis estimated the QALYs for stage IIIB/IV relapsed NSCLC patients receiving erlotinib (Tarceva®) and docetaxel.
Methods: A health state transition model was constructed to stratify patient survival between progression-free survival (PFS) and progressive disease; grade 3/4 adverse events (AEs) were also incorporated. The time in each health state was weighted by published NSCLC utility scores to estimate the QALYs for both erlotinib and docetaxel. This analysis required estimates of survival and health-related QoL (represented by utility scores) for each intervention. QoL was derived from a NSCLC QoL study that estimated utility scores using the EuroQoL 5-Domain (EQ-5D) instrument (Tabberer M et al, Value Health 2006;9:A298). OS was based on phase III randomised, controlled trials, with a mean OS of 9.56 months assumed for erlotinib (Shepherd F et al, NEJM 2005;353:123) and 8.74 months for docetaxel (Hanna N et al, J Clin Oncol 2004;22:1589). Since mean PFS was not reported for docetaxel, the mean time on treatment reported in the trials was used to represent PFS (4.11 and 2.76 months for erlotinib and docetaxel, respectively). The incidences of grade 3/4 treatment-related AEs were also as reported in the clinical trials.
Results: Erlotinib was estimated to produce higher QALYs than docetaxel; 0.277 vs 0.210, which equates to 101 and 77 quality-adjusted days for erlotinib and docetaxel, respectively. When equivalent OS and PFS were assumed, the advantage for erlotinib in terms of QALYs persisted, due to a lower incidence of treatment-related AEs such as febrile neutropenia.
Conclusions: Erlotinib produces greater QALYs compared with docetaxel, and hence provides a valuable alternative to docetaxel in the treatment of relapsed NSCLC. This analysis also illustrates that when NSCLC treatments lead to comparable OS, the QALY can help to differentiate between interventions with different AE and QoL profiles.

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Gemcitabine and docetaxel in non-small cell lung cancer (NSCLC) and study of prognostic factors

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Lung cancer is the most important cancer in the world in term of incidence and mortality. Cisplatin-based chemotherapy represents the cornerstone treatment for advanced and metastatic NSCLC. However, cisplatin has severe toxicity (renal, neural and oto-toxicity) wich remains a significant clinical problem.
We conducted a prospective study to compare the efficacy, the toxicity and survival of two regimens of chemotherapy with and without platinum in stage III and IV non-small cell lung cancer.
Eighty (80) patients were included in this study (72 males, 8 females); the median age was 58.6 years, 40 patients in each arm. They received in:
Arm A: G-D gemcitabine 1250 mg/m^2 D1 and D8 + docetaxel 70 mg/m^2 D8 repeated every 3 weeks for six courses.
Arm B: C-P cisplatin 70 mg/m^2 D1 + paclitaxel 175 mg/m^2 D1 repeated every 3 weeks for six courses.
There was no significant difference in term of response and survival between DC and CP, suggesting the equivalent efficacy of the two regimens. In terms of toxicity, the two arms are comparable except for the asthenia and anemia.
Performans status and nodes status are prognostic factor for survival for patients with non-small-cell lung cancer. Biomarquers such as p53, EGFR, cell proliferation defined by ki67 does not seem to be in correlation with survival.
Larger and longer follow-up studies may be needed to determine the prognostic role of expression of those factors in NSCLC.

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Efficacy of weekly docetaxel combined with platinum as 1st-line treatment in patients with advanced non-small cell lung cancer

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Background: Docetaxel is a highly effective chemotherapeutic agent with proven efficacy in non-small cell lung cancer (NSCLC). However, myelosuppression can be a substantial concern when docetaxel is administered every 3 weeks. Weekly administration of low-dose docetaxel has demonstrated comparable efficacy together with a distinct toxicity profile with reduced myelosuppression. We conducted a phase II study of weekly docetaxel and cisplatin or carboplatin in patients with advanced NSCLC to evaluate efficacy and safety.
Methods: Twenty-nine patients with advanced or metastatic NSCLC who had not received prior treatment were enrolled. The patients received intravenous infusions of docetaxel (35 mg/m^2, days 1, 8, 15) and cisplatin (75 mg/m^2, day 1) or carboplatin (AUC 6), followed by a week of rest.
Results: Twenty-six patients were assessable for efficacy and all patients assessable for toxicity. The overall response rate was 44.8%. The median survival was 11.3 months, and the 1-year survival rate was 37%. Of the hematologic toxicities, grade 3/4 neutropenia were observed in 12.6%, but there were no episodes of neutropenic fever. Non-hematologic toxicities were mild.
Conclusions: With weekly dosing, though efficacy is comparable, myelosuppression is substantially less, and the overall tolerability profile is better than with every 3 weeks dosing.

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A phase II study of the combination chemotherapy of docetaxel and carboplatin in advanced non-small cell lung cancer

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Background: To evaluate the efficacy and safety of induction chemotherapy with docetaxel and carboplatin in advanced lung cancer.
Methods: Between January 2005 and January 2007, 54 patients were enrolled and evaluable. Patients were treated with Docetaxel 75 mg/m^2 and Carboplatin AUC 5 on day 1 every 21 days.
Result: Among the 54 patients, 51 were male. The median age was 62 (range 23−79) years old. Pathologically, 20 patients had adenocarcinoma,