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Sponsor/company:	sanofi-aventis	ClinialTrials.gov Identifier:	NCT00772863
		Study Code:	XRP6976I_6012
Generic drug name:	Docetaxel	Date:	16 October 2009

Title of the study:	Evaluation of Efficacy and Safety of Sequential Cisplatin and Docetaxel Chemotherapy in the First Line Treatment of Advanced Stage Epithelial Ovarian Cancer: Phase II Clinical Trial		
Coordinating Investigator(s):	Nilüfer Güler, Prof. MD University of Hacettepe, Faculty of Medicine, Institute of Medical Oncology, Ankara		
Study center(s):	Three centers in Turkey were enrolled in this study.		
Publications (reference):	NA		
Study period: Date first patient enrolled: 17-Sep-2003 Date last patient completed: 07-Aug-2008		Phase of development: II	
Objectives:	Primary Objectives: • To determine the efficacy of sequential cisplatin –docetaxel chemotherapy using objective (clinical, radiological, pathological and biochemical) response rates • To evaluate the safety of treatment Secondary Objectives: • To evaluate time to disease progression or relapse: "progression-free survival" (PFS) • To evaluate survival time: "overall survival" (OS) • To evaluate the quality of life.		
Methodology:	A prospective, national, open label, multi-center, non-comparative, phase II clinical study.		
Number of patients:	Planned: 50	Randomized: NA	Treated: 36 patients
Evaluated:	36 patients	Safety: 36 patients	
Diagnosis and criteria for inclusion:	Patients, aged between 18-70 years, with histologically/cytologically confirmed and optimally resected Stage III-IV epithelial ovarian cancer, with an ECOG performance status of 0-2, with an acceptable hematological profile and adequate renal and liver function tests, were enrolled in the study.		

Investigational product: Dose: Administration:	Docetaxel and cisplatin Docetaxel and cisplatin, 100 mg/m^2 each 8 cycles of treatment was administered in every 21 days. Following adequate hydration, cisplatin was administered at a dose of 100 mg/m^2 with 2-hr iv infusion at the 1st day of treatment, for a total of 4 cycles in every 3 weeks. Docetaxel therapy was initiated 3 weeks after the 4th cycle of cisplatin treatment in all patients. Docetaxel was administered at a dose of 100 mg/m^2 with 60-min iv infusion, for a total of 4 cycles in every 3 weeks.
Duration of treatment: 22 weeks	Duration of observation: 31.1 months
Reference therapy: Dose: Administration:	NA NA NA
Criteria for evaluation:	The current report is an abbreviated report, and as such, only the safety results are being presented in full. The following safety criteria were evaluated, and analyzed using descriptive statistics. All adverse events were recorded. Toxicities were evaluated according to NCI-CTC criteria.
Statistical methods:	Descriptive statistics were performed for the evaluation of efficacy and safety. Objective response was calculated in percentages and survival rate was calculated using Kaplan-Meier survival analysis. In multivariate analyses, response rates were evaluated using logistic regression and survival rates using Cox regression analysis, when required.
Summary:	The study was planned to be conducted in 3 centers with 50 patients, however in the anticipated time period 36 patients could be enrolled into the study and the targeted sample size could not be reached due to slow recruitment, leading to the early termination of the study. A total of 36 Stage III-IV epithelial ovarian cancer patients were enrolled. All included patients had cisplatin treatment and 91.7% of patients received 4 cycles of cisplatin (n=33). One of three patients received 3 cycles, one received 2 cycles and one received only 1 cycle of cisplatin treatment. Totally, 32 patients had docetaxel therapy and 83% of patients received 4 cycles of docetaxel (n=30). Two patients had only 1 cycle of docetaxel treatment. Therefore 30 patients completed all 8 cycles of cisplatin-docetaxel treatment. Overall response rate of 27 evaluable patients who received 4 cycles of cisplatin treatment was 85.2% (n=23). Complete response rate was 55.6% (n=15) and partial response rate was 29.6% (n=8). Six patients who completed all cisplatin cycles could not be evaluated in terms of treatment response. Overall response rate of 26 evaluable patients who had 4 cycles of sequential docetaxel treatment was 73% (n=19). After sequential docetaxel treatment, 61.5% of evaluable patients had complete (n=16) response and 11.5% of them (n=3) had partial response. Four patients who completed 4 docetaxel treatment cycles could not be evaluated in terms of response. When all the patients included in the study were analyzed, the median follow-up time was 31.1 months. The median progression-free survival time was 16.07 months (95% CI 6.65-25.49 months) and overall survival time was 35.87 months (95% CI 22.40-49.34 months). The median progression-free survival time was 21.10 months (95% CI 16.65-25.55 months) in patients who had no tumor in SLL and the median progression-free survival time was 10.93 months (95% CI 7.01-14.86 months) in patients who had tumor in SLL. The median progression-free survival time of the patients with tumor in the SLL was significantly shorter than the patients without tumor (p=0.009).

	The Quality of Life evaluated before the study, after cisplatin and after docetaxel treatments were compared. Nausea and vomiting scores were significantly higher after cisplatin treatment ($p<0.01$), pain significantly decreased after the treatments ($p=0.031$) and cognitive function improved significantly after the treatments ($p=0.053$). Totally 213 adverse events were observed during the study. The most common adverse events were nausea and numbness in the hands and feet. Overall 11 serious adverse events, including deaths, were observed. Toxicity evaluations according to NCI-CTC demonstrated a total of 12 grade 3 and grade 4 toxicities. One death occurred during the treatment period, and 16 deaths occurred during the follow-up period. Death rate was found to be 2.8% during the treatment period.
Date of report:	5-Oct-2009