

## **Gemcitabine and oxaliplatin (GEMOX) in patients with cisplatin-refractory germ cell tumors: a phase II study.**

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### **Source**

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### **Abstract**

#### **BACKGROUND:**

To investigate the efficacy and toxicity of the combination of gemcitabine and oxaliplatin (GEMOX) in patients with relapsed or cisplatin-refractory non-seminomatous germ cell tumors (NSGCT).

#### **PATIENTS AND METHODS:**

Twenty-nine patients with relapsed or cisplatin-refractory NSGCT were treated with gemcitabine 1000 mg/m<sup>2</sup> on days 1 and 8 followed by oxaliplatin 130 mg/m<sup>2</sup> on day 1 every 3 weeks for a maximum of six cycles. Twenty-four patients (83%) were considered refractory and five (17%) absolutely refractory to cisplatin.

#### **RESULTS:**

Twenty-eight patients were assessable for response. Overall, nine patients (32%) achieved a favourable response (complete response, four; partial response, five). One of the complete responders relapsed after 7 months and went into disease-free status lasting for 11+ months after resection of lung metastases. The rest of the complete responders are continuously disease-free at 14+, 19+ and 28+ months with the study regimen plus or minus surgery. One of the complete responders had absolutely cisplatin-refractory disease and another one presented with a late relapse. Toxicity was primarily hematological and generally manageable: 62% of patients experienced grade 3/4 neutropenia, 10% neutropenic fever and 41% grade 3/4 thrombocytopenia. Non-hematological toxicity consisted mainly of nausea/vomiting. Three patients (10%) developed grade 3 neurotoxicity and discontinued treatment.

#### **CONCLUSIONS:**

The combination of GEMOX is an active, moderately toxic and easily administered regimen in patients with relapsed or cisplatin-refractory NSGCT. The 14% long-term disease-free status accomplished in this heavily pretreated patient population is quite encouraging.