

**Vinorelbine in combination with interleukin-2 as second-line treatment in patients with metastatic melanoma. A phase II study of the Hellenic Cooperative Oncology Group.**

[Gogas H](#), [Bafaloukos D](#), [Aravantinos G](#), [Fountzilias G](#), [Tsoutsos D](#), [Panagiotou P](#), [Frangia K](#), [Kalofonos HP](#), [Briasoulis E](#), [Castana O](#), [Polyzos A](#), [Pectasides D](#), [Ioannovich J](#); [Hellenic Cooperative Oncology Group](#).

**Source**

First Department of Medicine, University of Athens, Athens, Greece. hgogas@hol.gr

**Abstract**

**OBJECTIVES:**

To evaluate the efficacy and toxicity of the combination of vinorelbine and interleukin (IL)-2 in patients with metastatic melanoma as second-line chemotherapy.

**PATIENTS AND METHODS:**

Twenty-two patients with histologically confirmed stage IV melanoma previously treated with temozolomide-based chemotherapy--only one regimen of chemotherapy for disseminated disease was allowed--were treated with vinorelbine 30 mg/m<sup>2</sup> on days 1 and 15 and IL-2 subcutaneous 9 x 10<sup>6</sup> once daily on days 2-6 and 16-19 every 4 weeks for maximum of six cycles.

**RESULTS:**

From January 2000 to July 2001, 22 patients entered the study; the median age was 56 years. Among 20 evaluable patients there were 2 (9.1%) objective responses including 1 complete response and 1 partial response. Five (22.7%) had stabilization of their disease, and 13 (59.1%) progressed. The median time to progression (TTP) was 2.9 months and the median overall survival was 9.1 months. There was a significant difference in TTP in patients who responded or remained stable (median TTP 10.75 months) and those who progressed (median TTP 2.1 months) ( $p < 0.05$ ). There was also a difference in survival in the two groups ( $p < 0.05$ ) (28 vs. 8 months). The most common side effects were flulike symptoms, such as fever, chills, fatigue, and injection site reaction. Grade 3 hematological toxicity rarely occurred. One patient discontinued therapy because of fatigue and anorexia. There were no treatment-related deaths.

**CONCLUSIONS:**

The combination of vinorelbine and IL-2 provides clinical benefit in patients recurring or progressing on first-line chemotherapy for metastatic melanoma, with manageable toxicity.