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**Irinotecan and oxaliplatin combination, as second-line treatment, in fluoropyrimidine-pretreated advanced colorectal cancer. A phase II study by the Hellenic Cooperative Oncology Group (HeCOG).**

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**Source**

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**Abstract**

**BACKGROUND:**

The management of patients with fluoropyrimidine-resistant advanced colorectal cancer remains Investigational. Irinotecan and oxaliplatin have proved effective in first-line treatment in combination with 5-fluorouracil.

**STUDY DESIGN:**

From February 1998 to September 2002, 34 patients with 5-fluorouracil-pretreated advanced colorectal cancer were enrolled in the study. Median age was 67 years (range, 32-76) and median performance status was 1. Twenty-one patients had multiple liver metastases. Other sites of disease included lungs, abdomen, pelvis, lymph nodes, bones and skin. They received six 28-day cycles of oxaliplatin (85 mg/m<sup>2</sup> in a 2-h infusion on days 1 and 15) and irinotecan (80 mg/m<sup>2</sup> in a 30-minute infusion on days 1, 8 and 15 immediately following oxaliplatin).

**RESULTS:**

Thirteen patients (39%) completed treatment. The most common grade III-IV toxicities were diarrhea (27%), anemia (6%), neutropenia (18%), alopecia (6%) and peripheral neuropathy (6%). Thirteen patients (39%) received G-CSF support, and there were 2 episodes of febrile neutropenia. There were no treatment-related deaths. Six patients (18%) had a partial remission and another 11 (33%), disease stabilization. There were no complete remissions. Median time to progression was 6.6 months (range, 0.8-20.1) and median survival 10.6 months (range, 0.8-52.9).

**CONCLUSIONS:**

Irinotecan and oxaliplatin combination has modest activity as second line treatment of 5-fluorouracil-resistant advanced colorectal cancer. Further research is warranted for the development of more effective and less toxic regimens in this setting.