

Phase II study of 5-fluorouracil and interferon-gamma in patients with metastatic colorectal cancer. A Hellenic Cooperative Oncology Group Study

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Source

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Abstract

Preclinical data have shown a synergism between 5-fluorouracil and interferon-gamma against human colon carcinoma cell lines. We conducted a phase II trial of this combination in 34 patients with metastatic colorectal cancer. 5-Fluorouracil was administered as an intravenous bolus of 500 mg/m² weekly and interferon-gamma subcutaneous injection at a dose of 200 micrograms (6 x 10⁶ IU) 3 times a week. Thirty-two patients were evaluable for response. There was one complete and two partial responses (response rate 9.0%, 95% CI 1.98-25.02%). Eleven patients (34%) had stable disease. Common toxicities included fever 81%, nausea/vomiting 19%, diarrhea 16%, flu-like syndrome 16%, malaise 12.5% and leukopenia 12.5%. These results indicate that the above combination of 5-fluorouracil and interferon-gamma has an unimpressive activity in patients with advanced colorectal carcinoma. Toxicity was very tolerable.