

[Am J Clin Oncol](#). 2002 Feb;25(1):23-30.

A phase III study of 5-fluorouracil versus 5-fluorouracil plus interferon alpha 2b versus 5-fluorouracil plus leucovorin in patients with advanced colorectal cancer: a Hellenic Cooperative Oncology Group (HeCOG) study.

[Kalofonos HP](#), [Nicolaidis C](#), [Samantas E](#), [Mylonakis N](#), [Aravantinos G](#), [Dimopoulos MA](#), [Gennatas C](#), [Kouvatseas G](#), [Giannoulis E](#), [Dervenis C](#), [Basdanis G](#), [Pavlidis N](#), [Androulakis I](#), [Fountzilas G](#); [Hellenic Cooperative Oncology Group \(HeCOG\)](#).

Source

Department of Medicine/Oncology, University Hospital of Patras, Rion 26500, Greece.

Abstract

We conducted a phase III study in patients with advanced colorectal carcinoma (ACC). The total number of patients randomized from October 1993 until July 1998 was 192, whereas therapy was started on 179 and 158 (82.3%) have been evaluable. The treatment schedules consisted of weekly bolus administration for 6 weeks of 5-fluorouracil (5-FU), 600 mg/m² (arm I) versus 5-FU (500 mg/m²) intravenous bolus and interferon-alpha, 5 MU subcutaneously, three times a week (arm II) versus leucovorin 200 mg/m² in 2-hour infusion and 5-FU 500 mg/m² intravenous bolus at the midtime of leucovorin infusion (arm III) followed by a 2-week rest period. Treatment was continued for six cycles or until progression. This study failed to show any superiority of the modulated 5-FU versus single administration of 5-FU. There were no significant differences between the three arms in the overall response rate (10.3% versus 11.3% versus 12.9%, $p = 0.95$), the time to tumor progression (median, 3.9 versus 3.8 versus 6.0 months, $p = 0.59$), or survival duration (median, 14.7 versus 12.4 versus 16.3 months, $p = 0.71$). The incidence of severe (grades III and IV) toxicity was significantly higher in patients in arm II and III (24.5% and 18.6%) versus arm I (6.0%) ($p = 0.01$). Because modulated 5-FU failed to show superiority versus 5-FU, new agents and new strategies are needed for the treatment of advanced colorectal carcinoma.