A randomised phase III trial of adjuvant radio-chemotherapy comparing Irinotecan, 5FU and Leucovorin to 5FU and Leucovorin in patients with rectal cancer: a Hellenic Cooperative Oncology Group Study.

Kalofonos HP, Bamias A, Koutras A, Papakostas P, Basdanis G, Samantas E, Karina M, Misailidou D, Pisanidis N, Pentheroudakis G, Economopoulos T, Papadimitriou C, Skarlos DV, Pectasides D, Stavropoulos M, Bafaloukos D, Kardamakis D, Karanikiotis C, Vourli G, Fountzilas G; Hellenic Cooperative Oncology Group Study.

Source

Department of Medicine, Division of Oncology, University Hospital, University of Patras Medical School, Rion 26504, Patras, Greece. kalofon@med.upatras.gr

Abstract

The primary objective was to compare the 3-year survival of rectal cancer patients randomised postoperatively to irinotecan (IRI), Leucovorin (LV) and bolus 5-fluorouracil (5FU) or LV-bolus 5FU with radiotherapy. Secondary objectives included disease-free survival, local relapse and toxicity. The study included 321 eligible patients. The treatment consisted of weekly administration of IRI 80 mg/m(2) intravenously (IV), LV 200 mg/m(2) and 5FU 450 mg/m(2) bolus (arm A) versus LV 200 mg/m(2) and 5FU 450 mg/m(2) IV bolus (arm B). One cycle included four infusions and treatment was continued for a total of six cycles. The first cycle was followed by pelvic irradiation plus 5FU. There were no differences between the arms in 3-year overall, disease-free and local relapse-free survival. Grades 3 and 4 toxicity was similar in both the arms with the exception of leucopaenia, neutropaenia and alopecia, which were higher in the IRI arm. IRI added to adjuvant radiochemotherapy with LV and bolus 5FU was not shown to improve survival, whereas the incidence of severe leucopaenia was significantly higher in the IRI arm.

Comment in

- Eur J Cancer. 2008 Aug;44(12):1620-1.