Multicenter phase-II trial of irinotecan plus oxaliplatin [IROX regimen] in patients with poor-prognosis cancer of unknown primary: a hellenic cooperative oncology group study.

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Source

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Abstract

BACKGROUND:

Cancer of unknown primary (CUP) lacks established therapy although it affects 3% of cancer patients. We evaluated the irinotecan-oxaliplatin combination (IROX regimen) in previously untreated patients with non-favorable subsets of unknown primary carcinomas.

METHODS:

This was a multicenter phase-II trial. Protocol treatment consisted of oxaliplatin 80 mg/m(2) followed by irinotecan 160 mg/m(2) administered every 3 weeks. The primary end points were response rate and toxicity, and secondary end points were time to progression and survival.

RESULTS:

Forty-seven patients with liver, bone or multiple visceral metastases entered into the trial and received a median 6 chemotherapy cycles (1-11). The regimen was very well tolerated with one febrile neutropenia case and six cases with diarrhea grade 3 (16%). In intent-to-treat analysis the tumor response rate was 13% (95% CI = 4.8-25.7%) and 12 patients (27%, 95%CI 13.9-40.4%) had at least 4 months' duration of disease stabilization. The median time to progression was 2.7 months and the median survival was 9.5 months, with 40% of patients alive at 1 year.

CONCLUSIONS:

The IROX regimen demonstrated similar efficacy and a favorable toxicity profile compared to other more toxic chemotherapy combinations in patients with poor-prognosis CUP.