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XELIRI-bevacizumab versus FOLFIRI-bevacizumab as first-line treatment in patients with metastatic colorectal cancer: a Hellenic Cooperative Oncology Group phase III trial with collateral biomarker analysis.

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Source

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Abstract

BACKGROUND:

The aim was to compare two standard chemotherapy regimens combined with bevacizumab as first-line treatment in patients with metastatic colorectal cancer.

METHODS:

Patients previously untreated for metastatic disease were randomized in: group A (irinotecan, capecitabine, bevacizumab, every 3 weeks; XELIRI-bevacizumab) and group B (irinotecan, leucovorin, fluorouracil, bevacizumab, every 2 weeks; FOLFIRI-bevacizumab). Primary endpoint was progression-free survival (PFS). Plasma concentrations of nitric oxide, osteopontin, TGF-β1 and VEGF-A were measured at baseline and during treatment.

RESULTS:

Among 285 eligible patients, 143 were randomized to group A and 142 to group B. Fifty-five patients (38.5%) in group A and 57 (40.1%) in group B responded ($p = 0.81$). After a median follow-up of 42 months, median PFS was 10.2 and 10.8 months ($p = 0.74$), while median OS was 20.0 and 25.3 months ($p = 0.099$), for groups A and B, respectively. Most frequent grade 3-4 toxicities (group A vs group B) were neutropenia (13% vs 22%, $p = 0.053$) and diarrhea (19% vs 11%, $p = 0.082$). Baseline plasma osteopontin concentrations demonstrated prognostic significance for both PFS and OS.

CONCLUSIONS:

This trial did not show significant differences in efficacy between the groups. However, the toxicity profile was different. Baseline plasma osteopontin concentrations demonstrated independent prognostic significance. (Registration number: ACTRN12610000270011).