

Publication

Adding cetuximab to capecitabine plus oxaliplatin (XELOX) in first-line treatment of metastatic colorectal cancer : a randomized phase II trial of the Swiss Group for Clinical Cancer Research SAKK

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BACKGROUND: To determine the activity and tolerability of adding cetuximab to the oxaliplatin and capecitabine (XELOX) combination in first-line treatment of metastatic colorectal cancer (MCC). **PATIENTS AND METHODS:** In a multicenter two-arm phase II trial, patients were randomized to receive oxaliplatin 130 mg/m² on day 1 and capecitabine 1000 mg/m² twice daily on days 1-14 every 3 weeks alone or in combination with standard dose cetuximab. Treatment was limited to a maximum of six cycles. **RESULTS:** Seventy-four patients with good performance status entered the trial. Objective partial response rates after external review and radiological confirmation were 14% and 41% in the XELOX and in the XELOX + Cetuximab arm, respectively. Stable disease has been observed in 62% and 35% of the patients, with 76% disease control in both arms. Cetuximab led to skin rash in 65% of the patients. The median overall survival was 16.5 months for arm A and 20.5 months for arm B. The median time to progression was 5.8 months for arm A and 7.2 months for arm B. **CONCLUSION:** Differences in response rates between the treatment arms indicate that cetuximab may improve outcome with XELOX. The correct place of the cetuximab, oxaliplatin and fluoropyrimidine combinations in first-line treatment of MCC has to be assessed in phase III trials.

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