

## Calcium folinate + fluorouracil in advanced colorectal cancer

Antineoplastic therapy with fluorouracil + low-dose calcium folinate [leucovorin] affords statistically significant survival advantages over fluorouracil alone in patients with inoperable, locally advanced or metastatic colorectal cancer. This is the finding of the Swiss Group for Clinical Cancer Research who conducted the largest study of this nature published to date.

The group reports a median overall survival of 12.4 months among recipients of the combination regimen, compared with 10 months among monotherapy recipients. Median progression-free survival was 6.2 and 3.9 months, respectively.

Among 273 patients with measurable disease, the combination regimen also yielded a significantly higher clinical response rate than fluorouracil alone; the median duration of response was 10 and 7 months in the respective treatment groups. One-year actuarial survival was 53 and 43% with fluorouracil + calcium folinate vs fluorouracil alone, respectively.

### Treatment details

309 patients (26–82 years of age) who were ambulatory and had not received previous chemotherapy\* were randomised to treatment with either fluorouracil 400 mg/m<sup>2</sup>/day alone or low-dose calcium folinate 20 mg/m<sup>2</sup>/day followed by fluorouracil. Treatment courses were given via rapid IV bolus for 5 consecutive days and were repeated every 28 days. The fluorouracil dose was escalated to produce comparable toxicity in the 2 treatment arms.

No fatal toxicities occurred in this study. However, adding calcium folinate to fluorouracil resulted in a significant increase in WHO grade  $\geq 2$  stomatitis, nausea, diarrhoea, alopecia and other toxicities. If patients are offered the combination regimen, they should be informed about these potential adverse effects, say the researchers. The optimal fluorouracil schedule remains to be determined, they add.

*\* except adjuvant chemotherapy  $\geq 1$  year prior to this study*

Borner MM, Castiglione M, Bacchi M, Weber W, Swiss Group for Clinical Cancer Research (SAKK), et al. The impact of adding low-dose leucovorin to monthly 5-fluorouracil in advanced colorectal carcinoma: results of a phase III trial. *Annals of Oncology* 9: 535-541, May 1998

800688555