

Gemcitabine and vinorelbine as second-line treatment in patients with metastatic breast cancer progressing after first-line taxane-based chemotherapy: a phase II study conducted by the Hellenic Cooperative Oncology Group.

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Source

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Abstract

BACKGROUND:

Gemcitabine and vinorelbine have shown activity in breast cancer. A phase II trial was initiated in order to evaluate the response rate (RR) and time to progression (TTP) of the combination of the two drugs in patients with metastatic breast cancer progressing after first-line taxane-based chemotherapy.

PATIENTS AND METHODS:

Thirty-one patients were treated with the combination of gemcitabine 1000 mg/m² days 1 + 8 and vinorelbine 30 mg/m² days 1 + 8. The cycles were repeated every three weeks.

RESULTS:

Of 27 evaluable patients 1 (4%, 95% confidence interval (95% CI): 0.1%-19%) achieved complete remission (CR), five (18%; 95% CI: 6%-38%) partial remission (PR), eleven (40%; 95% CI: 22%-61%) stable disease and ten patients progressed. The median duration of response was six months (range 4-10+) and the median duration of disease stabilization was five months (range 2-22+). With a median follow-up of 16 months (range 0.4-22+) the median TTP was 3.5 months (range 0.4-22+) and the median survival was 9.5 months (range 0.4-22+). Grade 3-4 toxicities were granulocytopenia 15 patients (48%), rash 3 patients (10%), neuropathy 1 patient (3%) and thrombocytopenia 1 patient (3%). In conclusion the combination of gemcitabine/vinorelbine in the doses administered in this group of patients had a response rate of 22% and needs to be further evaluated in metastatic breast cancer.