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Vinblastine and interferon-gamma combination with and without 13-cis retinoic acid for patients with advanced renal cell carcinoma. Results of two phase II clinical trials.

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Abstract

BACKGROUND:

The aim of this study is firstly to determine the response rates and toxicity of two regimens containing vinblastine (VBL) in combination with interferon-gamma (IFN-gamma) in the treatment of patients with advanced renal cell carcinoma (RCC), and secondly to evaluate the additional efficacy of 13-cis retinoic acid (13-CRA) in RCC.

METHODS:

Twenty-nine patients were included in the first trial (Trial 1) and 40 in the second one (Trial 2). The therapy given in Trial 1 consisted of VBL 0.15 mg/kg i.v. every 2 weeks and IFN-gamma 100 microg s.c. 3 times weekly. In Trial 2, the therapy consisted of the same two drugs, in the same doses, plus oral 13-CRA 40 mg/day.

RESULTS:

In Trial 1 there were 3 (10.3%) patients with complete response, 3 (10.3%) patients with partial response, 8 (27.6%) patients with stable disease and 15 (51.7%) patients with progressive disease. In Trial 2, there was no complete response, however, 3 (7.5%) patients had partial response. Additionally, 15 (37.5%) patients maintained stable disease and 14 (35%) patients had progressive disease. In Trial 1, the median survival was 12.56 months (95% CI, 6.8-18.3, range 0.59-42.49) and the median time to progression was 3.21 months (95% CI, 1.7-4.7, range 0.03-42.49). In Trial 2, the median survival was 9.54 months (95% CI, 5.9-13.1, range 0.43-24.1) and the median time to progression was 3.9 months (95% CI, 0.8-7, range 0.26-24.1). In Trial 1, granulocytopenia grade 3 and 4 appeared in 5 (17.2%) patients and anaemia grade 3 in 1 (3.4%) patient. In Trial 2, there were grade 3 toxicities, as granulocytopenia in 5 (12.5%) patients, anemia in 4 (10.0%) patients, stomatitis in 3 (7.5%) patients, fatigue/malaise in 3 (7.5%) patients and 1 (2.5%) had diarrhea. No toxic deaths occurred in both studies.

CONCLUSION:

The use of IFN-gamma does not enhance the low response of VBL-based chemotherapy. The additional administration of 13-CRA with the combination of VBL and IFN-gamma does not add to the efficacy of this combination in patients with advanced renal cell carcinoma. New active agents are needed to treat patients with this disease.