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*Clinical Trials Summaries*

# Ifosfamide in Advanced Head and Neck Cancer. A Phase II Study of the Rotterdam Cooperative Head and Neck Cancer Study Group*

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A PHASE II study of ifosfamide 5 g/m$^2$ as a 24 h i.v. infusion, combined with mesna 400 mg/m$^2$ i.v. bolus every 4 h for nine doses commencing at the start of ifosfamide infusion, and with a 5 l dextrose/saline hydration during 36 h, was performed in pretreated patients with measurable advanced squamous cell cancer of the head and neck region. Cycles were to be repeated every 3 weeks. Response evaluation was performed according to WHO criteria. Eighteen patients were entered and 17 were evaluable (Table 1). Only one partial remission (6%) was achieved, while five patients (29%) had a stable disease of short duration. Median overall survival was only 4 months. Toxicity consisted of leucocytopenia (59%), alopecia (71%) and nausea/vomiting (71%). Neither renal nor CNS toxicity was observed. This ifosfamide regimen has only minor antitumor activity in heavily pretreated patients with head and neck cancer. Our study actually confirms the response data from three previous studies applying a 4-day administration regimen of ifosfamide [1–3].

Ifosfamide is not an attractive addition to the presently available therapeutic armentarium for head and neck cancer.

*Table* 1. *Patient characteristics*

| | |
|---|---|
| No. of evaluable patients | 17 |
| Age (years) | |
| median | 60 |
| range | 37–69 |
| Karnofsky index | |
| median | 80 |
| range | 60–100 |
| Primary tumor site | |
| oral cavity | 5 |
| pharynx | 6 |
| larynx | 6 |
| Metastatic sites | |
| lymph nodes | 7 |
| skin | 3 |
| lung | 3 |
| liver | 1 |
| local recurrence | 3 |
| Previous radiotherapy indicator | |
| lesion | 10 |
| Previous chemotherapy | |
| cisplatin | 12 |
| 5-fluorouracil | 8 |
| methotrexate | 3 |
| bleomycin | 2 |
| vincristine | 1 |

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