Head & Neck Oncology

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Photochemical internalization

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Introduction/aims

Photochemical internalization (PCI) is a novel technology facilitates the delivery of macromolecules into cytoplasm. The initial mechanism and practical application was described by Berg et al. in 1999.

This, first in human trial, is an open, phase I dose escalating study to evaluate the safety and tolerance of the photosensitizer (amphinex) that is used to initiate the photochemical internalization process with bleomycin as the chemotherapeutic agent. We present our preliminary report following the management of 11 patients with head and neck tumours.

Material/methods

Patients monitoring and follow-up start from Day -14 and continue to Day 28. The drug safety and tolerance are assessed by measuring the concentration (PK) of amphinex in plasma and urine after centrifugation and samples freezing under -20°C. Assessment of amphinex accumulation in skin is performed by fluorescence spectroscopy. Skin sensitivity testing is conducted using white light.

Results

The 11 patients in this trial received 0.25-1.0mg/kg amphinex (Day 0) approximately 93hrs prior to a slow bleomycin infusion (15000u/m^2) and subsequent illumination (Day 4) with 652nm diode laser with 60J/cm^2 to initiate PCI. No immediate clinical symptoms were reported prior to amphinex administration and no immediate drug adverse events were identified.

Conclusions

The most striking finding is the dramatic tumour responses. Complete tumour response of the target lesions of 10/11 patients was achieved. The starting dose of Amphinex for the study was set at a level not expected to trigger a PCI response, however there appeared to be a localized synergistic effect with photoactivation.

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