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Weekly docetaxel in minimally pretreated cancer patients: a dose-escalation study focused on feasibility and cumulative toxicity of long-term administration.

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Source

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Abstract

BACKGROUND:

Docetaxel is an agent with impressive clinical activity but a rather poor profile of toxicity when given every three weeks. Therefore, optimisation of its clinical use is highly warranted. This is a dose-escalation study of weekly docetaxel particularly focused on the feasibility of long-term administration and characterisation of cumulative toxicity.

PATIENTS AND METHODS:

Twenty-six patients (11 female/15 male, median age 56, range 23-73) were treated over the range of 25-50 mg/m2/week. Dose-limiting toxicity for this schedule was defined as any grade > 2 antiproliferative toxic effect resulting in a > 2-week delay for re-administration of the drug, or any grade > 2 organ-specific toxicity. Patients were monitored clinically and electrophysiologically for neurotoxicity. No prolonged corticosteroid co-medication or prophylactic haematopoietic growth factors were given.

RESULTS:

A median/mean number of 8.5/8.7 consecutive weekly courses were given per patient. The maximum tolerated dose that prevented on-schedule administration of the drug was 50 mg/m2. The main cumulative toxicities were a mild fluid retention and dacryorrhea which became evident as the number of treatment courses increased. Grade 2 alopecia and fatigue were observed only at 45 mg/m2 and higher. Activity was seen at all of the dose levels studied.

CONCLUSIONS:

Long-term weekly administration of docetaxel is feasible at doses up to 45 mg/m2/week with acceptable toxicity. Further clinical evaluation is justified at this schedule and 40 mg/m2/week of docetaxel is proposed for phase II studies as an active dose with minimal toxicity.