Toxicological study and efficacy of blank and paclitaxel-loaded lipid nanocapsules after i.v. administration in mice

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Résumé en anglais	PURPOSE: Lipid nanocapsules (LNCs) are solvent-free drug nanocarriers permitting entrapment of paclitaxel and increasing its antitumoural effect in animal models after i.v. injection. The tolerance and efficacy of LNCs after repeated dose i.v. administration were assessed in mice. The maximum tolerated dose (MTD) and 50 percent lethal dose (LD50) were studied.METHODS: Paclitaxel-loaded LNC formulation was given i.v. at the dose of 12 mg/kg per day for 5 consecutive days in comparison with blank LNCs and saline. Histological examination, complete blood counts and biochemical quantification were performed after a recovery of 7 days. Growth of NCI-H460 subcutaneous xenografts in nude mice receiving one of the aforementioned schedules was assessed. MTD and LD50 were determined by Irwin test. RESULTS: No mortality was observed in repeated injections studies. Histological studies revealed no lesions and no accumulation of lipids. Blood studies were normal. The tumoural growth was significantly reduced in the group treated by paclitaxel-loaded LNCs. The MTDs/LD50s of Taxol, paclitaxel-loaded LNCs and blank LNCs were 12/19.5, 96/216 and above 288/288 mg/kg, respectively. CONCLUSIONS: This study demonstrates that a five-day i.v. injection schedule of paclitaxel-loaded LNC dispersions induces no histological or biochemical abnormalities in mice and improves paclitaxel efficacy and therapeutic index in comparison with Taxol.
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