Long-term renal safety profile of ibandronate 6 mg infused over 15 minutes

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BACKGROUND: In an earlier study, intravenous (i.v.) ibandronate 6 mg administered every 3-4 weeks had a similarly good renal safety profile whether infused over 15 or 60 min in women with breast cancer and bone metastases. This current study focuses on the renal safety of the extended use of ibandronate. PATIENTS AND METHODS: Patients completing the original study could choose to enter a follow-up phase and continue (or switch) to receive ibandronate 6 mg by 15-min i.v. infusion every 3-4 weeks. The primary endpoint was the percentage of patients with a serum creatinine increase of >=44.2 mmol/l (= 0.5 mg/dl) from core baseline. RESULTS: Fourteen patients entered the follow-up phase and received a median of 16 infusions (range: 9-24). No patient reached the primary endpoint. Most adverse events were mild to moderate in intensity. None of the 6 reported treatment-related adverse events was considered severe or reported as a serious adverse event. CONCLUSIONS: Ibandronate was well tolerated when administered as a 6-mg i.v. infusion over 15 min every 3-4 weeks during the follow-up phase to the earlier core study. No evidence of any treatment-related deterioration in renal function was noted, and no new or unexpected adverse events occurred.