BACKGROUND: Clinical data show that a single, 15-min i.v. infusion of ibandronate 6 mg does not significantly alter renal function. We evaluated the effect on renal function of repeated 15-min infusions of ibandronate 6 mg in women with breast cancer and bone metastases. PATIENTS AND METHODS: Patients were randomly assigned to i.v. ibandronate 6 mg every 3-4 weeks for ≤6 months, infusion over 15 min (n = 102) or 60 min (n = 28). The primary end point was the percentage of patients with increased serum creatinine of ≥44.2 micromol/l. Blood chemistry was assessed at each visit. RESULTS: Two per cent [2/101; 95% confidence interval (CI) 0.2-7.0] of patients in the 15-min infusion arm and no patients (0/26; 95% CI 0.0-13.2) in the 60-min infusion arm had increased serum creatinine that met the primary end point. There were no clinically relevant changes in serum creatinine, creatinine clearance, or N-acetyl-beta-d-glucosaminidase, alpha(1)-microglobulin, or microalbuminuria. Most adverse events were mild or moderate. No clinically relevant changes were observed in vital signs, hematology, blood chemistry, or urine analysis. CONCLUSIONS: Ibandronate 6 mg by 15-min infusion every 3-4 weeks appear to be consistent with those renal safety profiles of 60-min infusion.