[2005] [FRI0360] INTRAVENOUS IBANDRONATE INJECTIONS ARE AT LEAST AS EFFECTIVE AS DAILY ORAL IBANDRONATE: CONSISTENT EFFECT ACROSS SUBGROUPS

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Background: I.v. bisphosphonates may be a new alternative for patients with postmenopausal osteoporosis (PMO) who cannot tolerate oral treatments. The DIVA study is investigating the efficacy and safety of novel intermittent i.v. ibandronate (Bonviva) injection regimens compared to daily oral dosing in PMO. After 1 year, substantial increases in lumbar spine BMD were observed with the investigational i.v. regimens (2mg every 2 months [2mg q2mo], 3mg every 3 months [3mg q3mo]) and approved oral comparator (2.5mg daily oral ibandronate; 3-year vertebral fracture risk reduction: 62%(1); Table) (2). Both i.v. regimens were proven non-inferior and superior ($p<0.001$) to the oral comparator for lumbar spine BMD gains (2).
Objectives: As treatment effects can vary depending on baseline patient characteristics, lumbar spine BMD gains were prospectively analysed across patient subgroups in DIVA.
Methods: Participants were receiving daily calcium (500mg) and vitamin D (400IU), plus 2mg q2mo or 3mg q3mo i.v. ibandronate injections or 2.5mg daily oral ibandronate. Lumbar spine BMD at 1 year was prospectively analysed in the overall study population and across patient subgroups (Table). No formal non-inferiority testing was performed for the subgroups. However, treatment effects versus the active comparator were evaluated post-hoc based on 95% confidence intervals. Only clinically relevant subgroups consisting ~20% of the overall patient population were considered.
Results: In the patient subgroups analysed (Table), increases in lumbar spine BMD were of a similar magnitude, and consistent with those observed in the overall study population (Table). Treatment effects were also similar between the i.v. regimens. For each patient subgroup analysed, both i.v. regimens met the criterion for non-inferiority (lower boundary of 95% CI >–1.0 [non-inferiority margin for overall population]; Table) versus the daily regimen.

Lumbar spine BMD (% from baseline [n]; 95% CI for difference vs daily) in subgroups

Patient group	2.5mg daily oral	2mg q2mo i.v.	3mg q3mo i.v.
Overall population (PP)	3.8 [377]	5.1 [353] (0.76, 1.86)	4.8 [365] (0.49, 1.58)
Baseline BMD <–2.5 to ≥ –3.0	3.4 [1.42]	4.4 [135] (0.14, 1.75)	4.3 [140] (0.03, 1.63)
Baseline BMD <–3.0 to ≥ –3.5	3.9 [117]	4.8 [104] (–0.10, 1.89)	5.1 [118] (0.24, 2.18)
Baseline BMD <–3.5 to ≥ –5.0	4.3 [118]	6.3 [114] (0.87, 3.03)	5.2 [107] (–0.21, 1.98)
No previous fracture*	3.7 [243]	5.0 [230] (0.61, 2.0)	4.7 [239] (0.34, 1.72)
Previous fracture*	4.0 [134]	5.3 [123] (0.42, 2.26)	5.0 [126] (0.16, 1.97)
Age <70 years	3.8 [268]	4.8 [227] (0.33, 1.67)	4.7 [256] (0.23, 1.53)
Age ≥ 70 years	3.9 [109]	5.8 [126] (0.89, 2.83)	5.3 [109] (0.38, 2.39)

*since age 45

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Conclusion: I.v. ibandronate injections (2mg q2mo, 3mg q3mo) are at least as effective as daily oral ibandronate for increasing lumbar spine BMD. Substantial and similar increases in lumbar spine BMD were observed in all patient groups indicating a consistent effect with ibandronate irrespective of baseline BMD, the presence of prevalent fracture and age.
References: 1. Chesnut CH, et al. J Bone Miner Res 2004;19:1241–9.
2. Recker RR, et al. ACR 2004.

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