[2008] [OP-0026] A SINGLE INFUSION OF ZOLEDRONIC ACID 5 MG IS SIGNIFICANTLY MORE EFFECTIVE THAN DAILY ORAL RISEDRONATE 5 MG IN INCREASING BONE MINERAL DENSITY OF THE LUMBAR SPINE, HIP, FEMORAL NECK AND TROCHANTER IN PATIENTS WITH GLUCOCORTICOID-INDUCED OSTEOPOROSIS

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Background: Prolonged use of glucocorticoids leads to bone loss and increased fracture risk[1]. Oral bisphosphonates increase bone mineral density (BMD) and reduce vertebral fracture risk in glucocorticoid-treated patients[2,3] but this mode of bisphosphonate administration is associated with poor compliance and persistence[4].
Objectives: To compare the efficacy and safety of intravenous zoledronic acid (ZOL) and oral risedronate (RIS) in the prevention and treatment of glucocorticoid-induced osteoporosis (GIO).
Methods: We performed a 1 year, randomised, double-blind, double-dummy study to evaluate the effects of intravenous ZOL (single 5 mg infusion) and oral RIS (5 mg/day) on lumbar spine (LS) BMD in two groups of glucocorticoid-treated patients (prevention subpopulation: ≤3 months of glucocorticoid treatment at randomisation [ZOL, n=144; RIS, n=144]; treatment subpopulation: >3 months of treatment at randomisation [ZOL, n=272; RIS, n=273]). The primary efficacy objective in each subpopulation was to demonstrate non-inferiority of ZOL relative to RIS in percentage change in LS BMD (baseline to 12 months). Secondary efficacy endpoints included percentage change in LS BMD at 6 months, and in femoral neck, total hip, and trochanter BMD at 6 and 12 months.
Results: Background characteristics were comparable between treatment groups within each subpopulation. The majority of patients were Caucasian (94.0%) and female (68.2%). ZOL increased LS BMD significantly more than RIS in both the treatment (ZOL, 4.1%; RIS, 2.7%; P=0.0001) and prevention (ZOL, 2.6%; RIS, 0.6%; P<0.0001) subpopulations at 12 months. ZOL was also significantly more effective than RIS in increasing BMD at 12 months at all other sites, which included femoral neck, trochanter, and total hip, in both subpopulations. The incidence of adverse events (AEs) within 3 days of treatment initiation was higher in ZOL-treated patients. This difference was mainly driven by increased incidence of the transient post-dose symptoms that are common after bisphosphonate infusion. Three days after the infusion, the two treatment groups had similar AE rates. The incidence of serious AEs was similar in the two treatment groups.
Conclusion: Over a 12–month period, a single 5 mg ZOL infusion was significantly more effective than daily RIS (5 mg/day) in increasing BMD at the lumbar spine and other sites in both the prevention and treatment of GIO.
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