

Rationale and Design of the MOTION Study (Monthly Oral Therapy with Ibandronate for Osteoporosis iNtervention)

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Active comparator studies are an accepted means for establishing the relative efficacy and safety of alternative treatment options. However, as clinical endpoints are often difficult to use (especially in chronic disease), comparison of validated surrogate markers is an accepted alternative. In light of its predictive value for fracture risk reduction within the class of bisphosphonates, the surrogate marker of change (%) in bone mineral density (BMD) has been used to establish the relative efficacy of weekly oral bisphosphonates in postmenopausal osteoporosis (PMO).¹ A similar comparative study (MOTION) is ongoing to compare the efficacy of once-monthly oral ibandronate, a potent, nitrogen-containing bisphosphonate with proven antifracture efficacy with extended dosing intervals, with weekly oral alendronate. In MOTION, a randomized, double-blind, double-dummy study, close to 1,900 women (55-84 years, ≥ 5 years postmenopause) with PMO (lumbar spine [L2-L4] BMD T-score < -2.5 and ≥ -5.0) will receive either 150mg once-monthly oral ibandronate or 70mg weekly oral alendronate for 1 year. To maintain blinding, participants will also receive once-monthly or weekly oral placebo, plus daily calcium (500-1,500mg) and vitamin D (400IU). The co-primary study endpoints are change (%) from baseline in lumbar spine and total hip BMD at 1 year. Subsequent non-inferiority tests will explore the comparable efficacy of the once-monthly and weekly oral regimens (non-inferiority margin: 1.14% and 0.87%, respectively). Secondary endpoints include change (%) in hip trochanter BMD at 1 year and the biochemical marker of bone turnover sCTX in a subset of patients (30%) at day 7 and months 3, 6 and 12. Adverse events will be monitored throughout the study. Clinical vertebral and non-vertebral fractures will also be assessed, and their respective rates compared. In summary, MOTION will explore the relative efficacy and safety of once-monthly oral ibandronate and weekly oral alendronate. Data from the MOTION study will further assist physicians in identifying the most appropriate treatment option in PMO.

1. Rosen C, et al. J Bone Miner Res 2005;20:141-51.

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