Effects of teriparatide and risedronate on new fractures in post-menopausal women with severe osteoporosis (VERO)

VERO SUBGROUP ANALYSIS

FORSTEO is superior vs risedronate in patients with prior and recent bisphosphonate use[1]

FORSTEO® teriparatide injection

Patients with prior and recent bisphosphonate use

Anti-resorptives, particularly bisphosphonates, are routinely used as first-line treatment of osteoporosis in post-menopausal women. Published data on the effect of sequential treatment regimens on new fracture outcomes are scarce.[2]

In the **VERO** subgroup analyses, no significant heterogeneity in the treatment effect of **FORSTEO** vs risedronate was demonstrated in patients defined by **prior bisphosphonate use or recent use of bisphosphonates.***[1]

IN VERO: 588 (43.2%) of all patients were treatment-naïve & 534 (39.3%) had recently been treated with bisphosphonates[1#]

PRIMARY ENDPOINT
NEW VERTEBRAL FRACTURES[1]

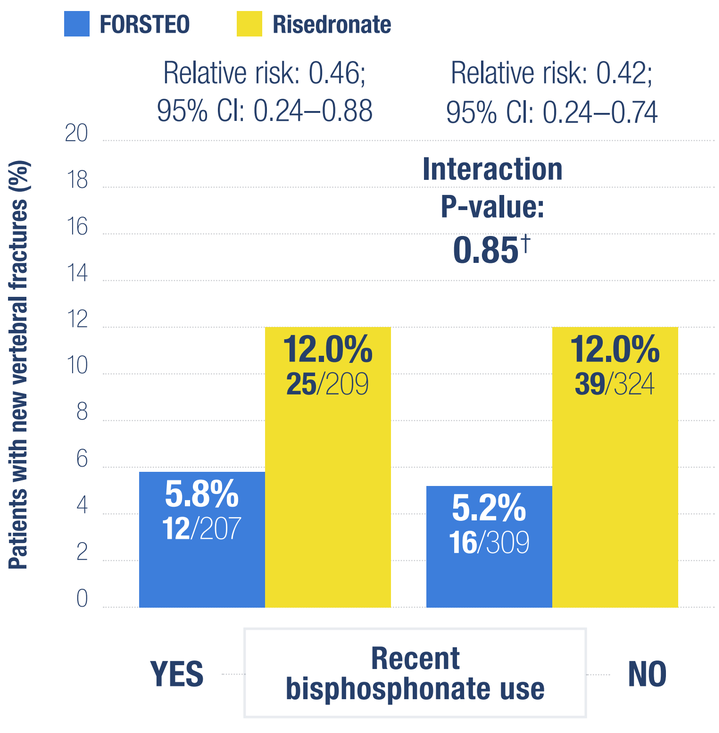
54%
relative risk reduction vs risedronate at 24 months in patients who had recently taken bisphosphonates

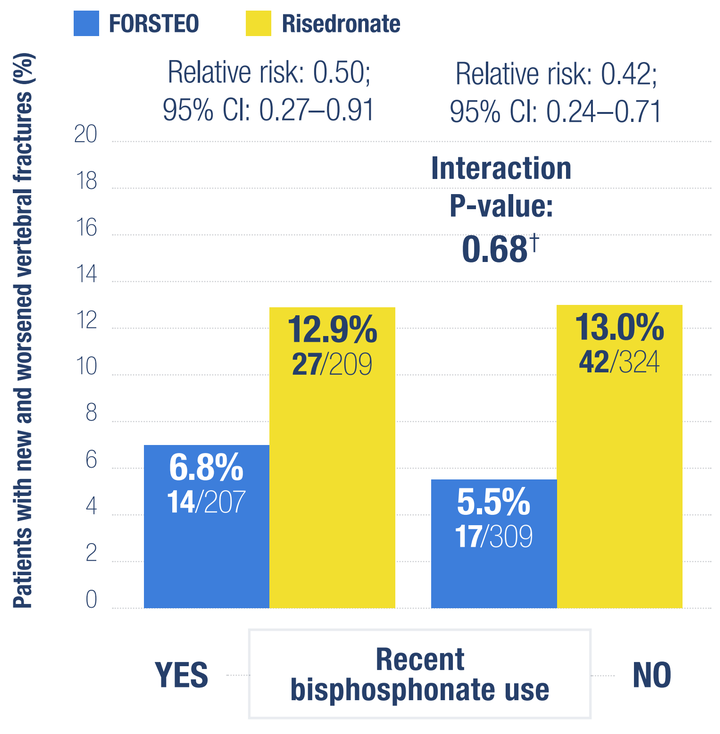
SECONDARY ENDPOINT
POOLED NEW AND WORSENED VERTEBRAL FRACTURES[1]

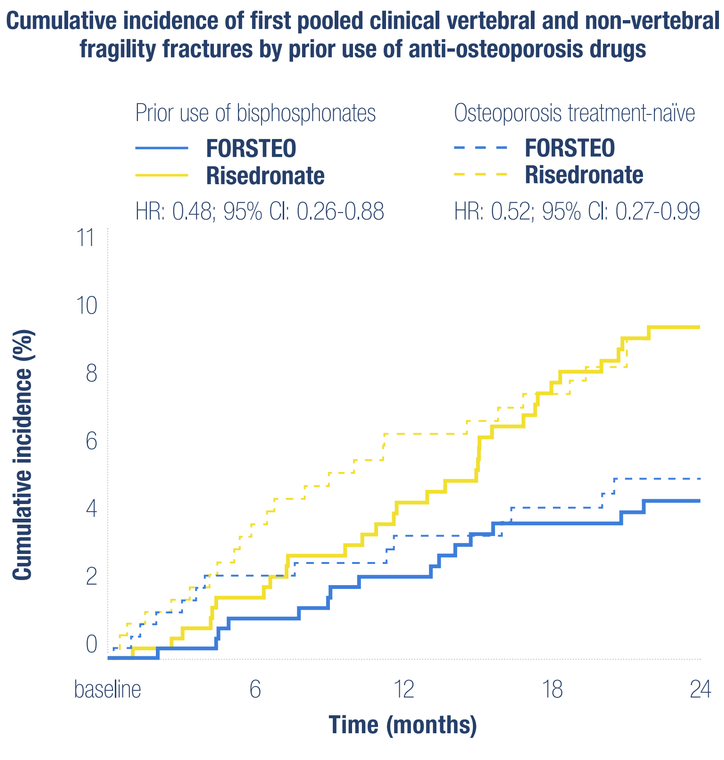
50%
relative risk reduction vs risedronate at 24 months in patients who had recently taken bisphosphonates

SECONDARY ENDPOINT
POOLED CLINICAL VERTEBRAL AND NON-VERTEBRAL FRAGILITY FRACTURES[1]

With FORSTEO, reduction in risk of clinical fractures was similar in bisphosphonate users (52%) and treatment-naïve patients (48%) at 24 months







Adapted from Geusens P, et al. J Bone Miner Res (2018)[##]

Adverse events were balanced across the two treatment groups with both drugs being well tolerated[3]

RELEVANCE TO CLINICAL PRACTICE

These results indicate the additional fracture benefit of using an anabolic as compared to an anti-resorptive drug across multiple patient clinical scenarios.

OTHER SECONDARY ENDPOINTS: Non-vertebral fragility fractures & major non-vertebral fragility fractures[1,3]

No statistically significant reduction in risk of non-vertebral fragility and major non-vertebral fragility fractures with FORSTEO vs risedronate in prior bisphosphonate users.

In post-menopausal women with osteoporosis and pre-existing vertebral fractures, treatment with **FORSTEO** reduced the relative fracture risk vs risedronate at 24 months in the following fracture endpoints:[3]

Relative risk reduction:

56% P<0.0001; ARR 6.6% — new vertebral fractures

54% P<0.0001; ARR 6.9% — pooled new and worsening vertebral fractures

52% P=0.0009; ARR 5.0% — pooled clinical vertebral and non-vertebral fractures

VERO PRIMARY ANALYSIS

FORSTEO is superior to risedronate in reducing the risk of new vertebral fractures during 24 months of therapy in post-menopausal women with severe osteoporosis[3]

Prospectively planned subgroup analyses of the VERO fracture data assessed potential heterogeneity in the treatment effect across nine clinically relevant patient subgroups.[1]

Download the VERO primary analysis paper

Download the VERO subgroup analysis paper

ARR, absolute risk reduction; CI, confidence interval; HR, hazard ratio

*Prior osteoporosis drug use was defined as per three different and mutually exclusive categories: prior bisphosphonate use, prior use of osteoporosis medication other than a bisphosphonate, no previous anti-osteoporosisdrug use. Treatment-naïve patients must not have received any anti-osteoporosis drugs or <3 months of anti-resorptive drugs. Recent bisphosphonate use was defined by: a) ≥6 months of treatment with any oral bisphosphonate – either intermittently or continuously – within 3 years of the screening visit, b) intravenous zoledronic acid at any dose within 2 years of the screening visit, and c) intravenous ibandronate or pamidronate at any dose within 12 months before the screening visit.

†A treatment-by-subgroup interaction P-value <0.1 was considered evidence of an effect modifier. These analyses were exploratory in nature and therefore the possibility of a true differential treatment effect for some subgroups cannot be ruled out due to lack of statistical power.

1. Geusens P, et al. J Bone Miner Res. 2018;33:783–794. **2.** Jakob F, et al. Eur J Endocrinol. 2012;166:87–97. **3.** Kendler DL, et al. Lancet. 2018;391:230–240.

* Full Analysis Set,
**Modified Analysis Set

Fachinformation

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