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 a recent clinical vertebral fracture[1]

FORSTEO® teriparatide injection

Patients with a recent clinical vertebral fracture

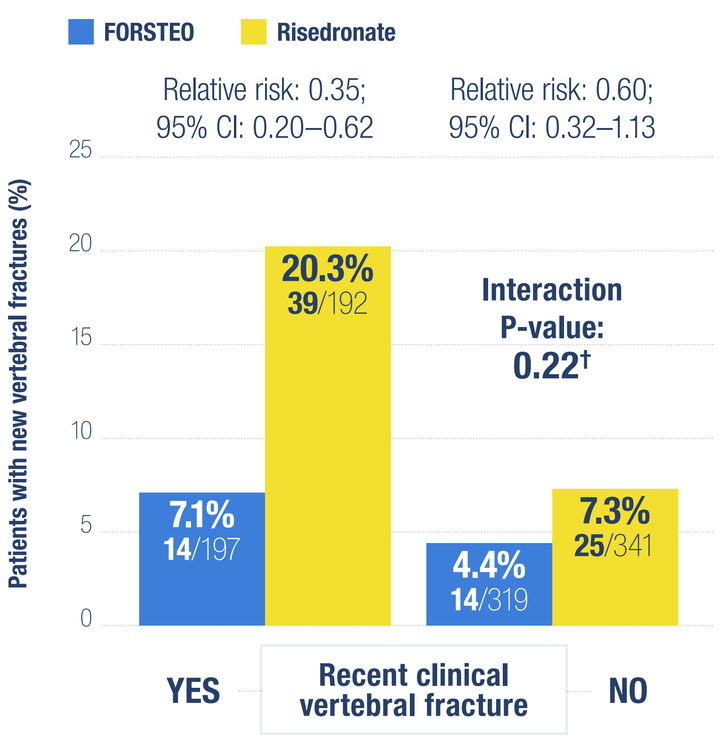
Post-menopausal women who have had a recent fracture are at **high risk of further imminent fractures.**[2]

In the **VERO** subgroup analyses, no significant heterogeneity in the treatment effect of **FORSTEO** vs risedronate was demonstrated in patients defined by a **recent clinical vertebral fracture.**[*1]

IN VERO: 496 (36.5%) patients had had a recent vertebral fracture[1#]

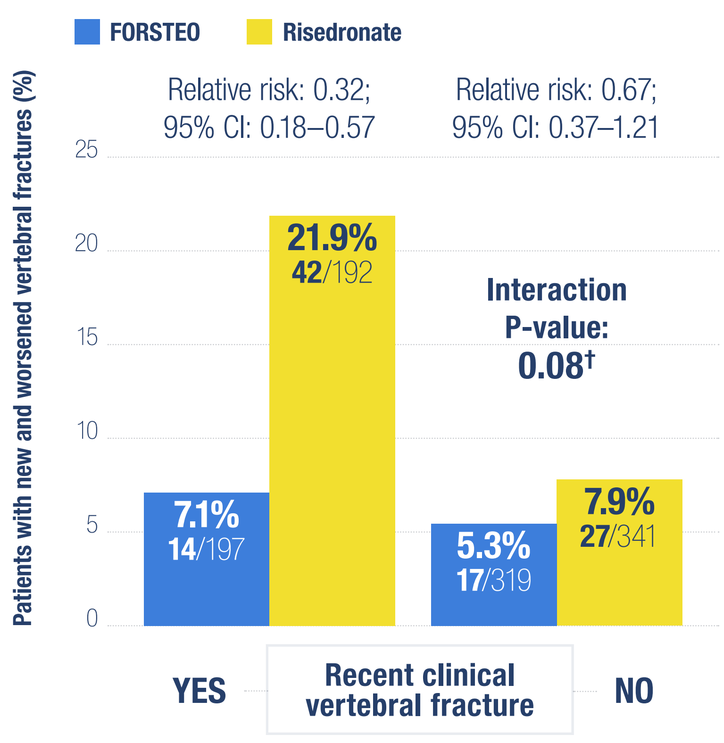
PRIMARY ENDPOINT
NEW VERTEBRAL FRACTURES[1]

65%
relative risk reduction vs risedronate at 24 months in patients with a recent vertebral fracture



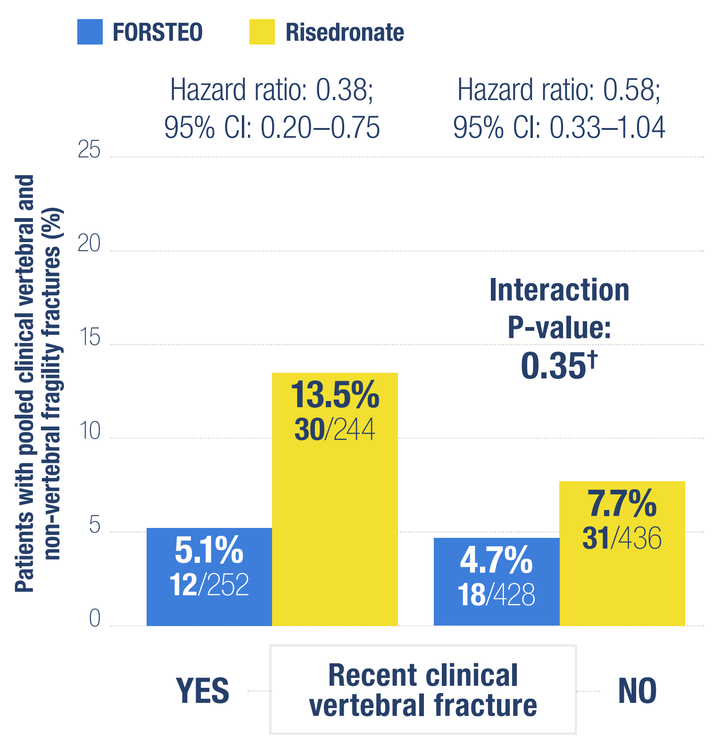
SECONDARY ENDPOINT
POOLED NEW AND WORSENED VERTEBRAL FRACTURES[1]

68%
relative risk reduction vs risedronate at 24 months in patients with a recent clinical vertebral fracture



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

62%
relative risk reduction vs risedronate at 24 months in patients with a recent clinical vertebral fracture



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]

The non-significant difference in treatment effect for FORSTEO vs risedronate observed in the overall analysis was not affected by a recent clinical vertebral fracture.

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

*A recent clinical vertebral fracture was defined as occurring 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. van Geel TA, et al. Ann Rheum Dis. 2009;68:99–102. 3. Kendler DL, et al. Lancet. 2018;391:230–240.

Full Analysis Set
Modified Analysis Set

Fachinformation

PP-TE-DE-0289 November 2018