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 BMD *T*-score <-2.5 SD[1]

FORSTEO® teriparatide injection

Patients defined by BMD *T*-score threshold

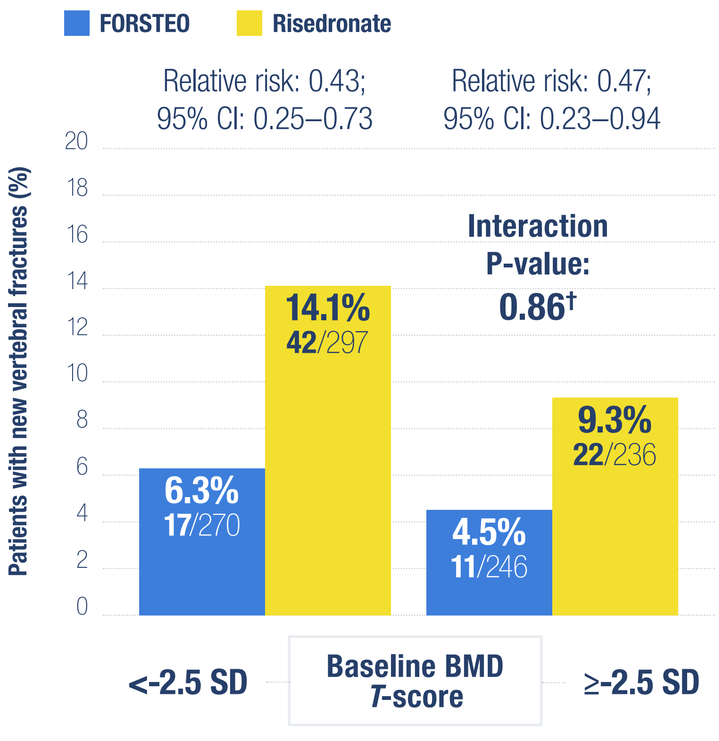
Osteoporosis is defined as a BMD 2.5 SD or more below the average value for pre-menopausal women (*T*-score <-2.5 SD).[2] There is a strong, continuous relationship between BMD and osteoporotic fractures.[3]

In the **VERO** subgroup analyses, no significant heterogeneity in the treatment effect of **FORSTEO** vs risedronate was demonstrated in patients defined by their **baseline BMD *T*-score.***[1]

IN VERO: 753 (55.4%) patients had a BMD *T*-score <-2.5 SD at baseline[1#]

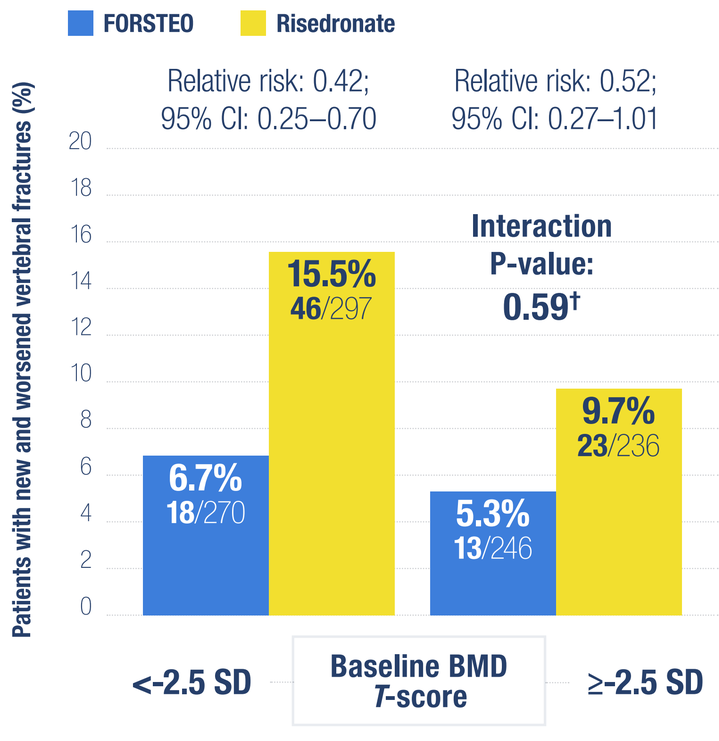
PRIMARY ENDPOINT
NEW VERTEBRAL FRACTURES[1]

57%
risk reduction vs risedronate at 24 months in patients with a baseline BMD *T*-score <-2.5 SD



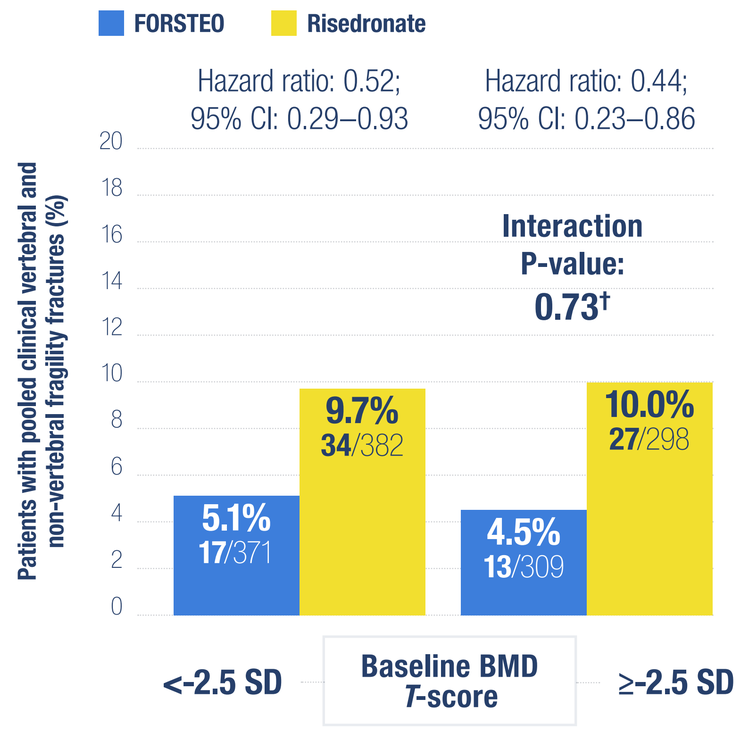
SECONDARY ENDPOINT
POOLED NEW AND WORSENED VERTEBRAL FRACTURES[1]

58%
relative risk reduction vs risedronate at 24 months in patients with a BMD *T*-score <-2.5 SD



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

48%
relative risk reduction vs risedronate at 24 months in patients with a BMD *T*-score <-2.5 SD



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[4]

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[1,4]

The non-significant difference in treatment effect for FORSTEO vs risedronate observed in the overall analysis was not affected by BMD *T*-score at baseline.

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:[4]

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[4]

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; BMD, bone mineral density; CI, confidence interval; SD, standard deviation

*BMD *T*-score at baseline was defined as per two categories: <-2.5 or ≥-2.5 SD measured at the spine and/or at the proximal femur.
†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.** Kanis JA. Lancet. 2002;359:1929–1936. **3.** Siris ES, et al. Arch Intern Med. 2004;24:1108–1112. **4.** Kendler DL, et al. Lancet. 2018;391:230–240.

* Full Analysis Set
** Modified Analysis Set

Fachinformation

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