

Increased risk of serious infections in women with osteopenia or osteoporosis treated with denosumab

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Dear Editors,

Results from the Fracture REduction Evaluation of Denosumab in Osteoporosis Every 6 Months (FREEDOM) trial suggest that denosumab reduces the risk of fractures in women with osteoporosis without increasing the risk of serious infections [1]. A recent meta-analysis reported a significantly increased risk of serious infections in women with osteoporosis or osteopenia treated with denosumab compared to controls [2]. Updating this meta-analysis [2] with the latest data from the FREEDOM trial [1], the risk of serious infections remained significantly higher for the denosumab group [Mantel–Haenzel risk ratio (M–H RR)=1.26, confidence interval (CI)=.01-1.57; $p=0.04$, $I^2=22.8\%$, Fig. 1]. This finding remained robust when Peto's method was used (Peto odds ratio=1.28, CI=1.02-1.60; $p=0.04$, $I^2=44\%$). When a trial in patients with non-metastatic breast cancer was excluded [3], the risk increase was found to be borderline significant (M–H RR=1.25, CI=1.00-1.59; $p=0.05$, $I^2=41\%$). Based on this evidence,

it appears that denosumab might be associated with an increased risk of serious infections.

Conflicts of interest None.

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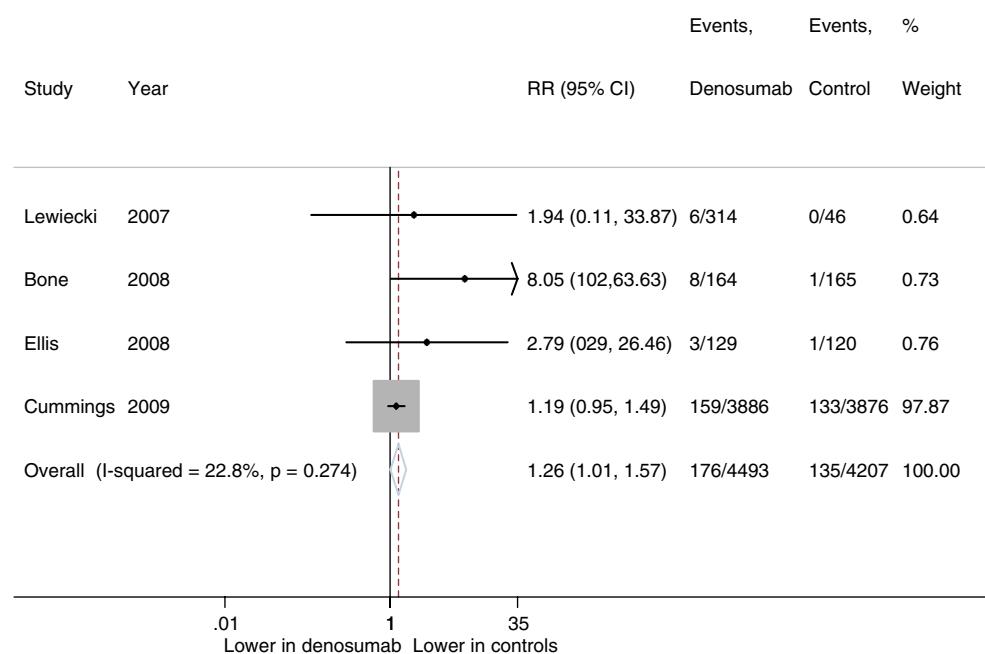
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Fig. 1 Risk ratio of serious infection in women with osteoporosis or osteopenia treated with denosumab compared to controls



Legend: Risk ratio of serious infection in women with osteoporosis or osteopenia treated with denosumab compared to controls.