Alendronate reduced days of bed rest and limited activity in postmenopausal women with osteoporosis and existing fractures


QUESTION: In postmenopausal women with osteoporosis and ≥1 vertebral fracture, does alendronate reduce back pain and functional limitation caused by back pain?

Design
3 year randomised (allocation concealed†)‡, blinded (patients, clinicians, and outcome assessors)§, placebo controlled trial (Fracture-Intervention Trial [FIT]).

Setting
11 clinical centres in the US.

Patients
2027 women who were 55–81 years of age (mean age 71 y), had been postmenopausal for ≥2 years, had a femoral neck bone mineral density ≤0.68 g/cm², and had ≥1 vertebral fracture. Follow up was 100%.

Intervention
Women were allocated to alendronate sodium, 5 mg/day for 2 years and 10 mg/day for the third year (n = 1022), or placebo (n = 1005).

Main outcome measures
Days of back pain and limited activity days related to back pain were assessed by questionnaire every 3 months. Physical disability related to back pain was assessed at 3 years by self report.

Main results
At 3 years, women in the alendronate group had lower cumulative incidence rates of ≥1 day of bed rest (p = 0.002) and ≥7 days of bed rest (p < 0.001) than did women in the placebo group; a trend toward a greater incidence of ≥7 limited activity days was seen in the alendronate group (p = 0.06) (table). The groups had similar rates of ≥1 day of severe or worse back pain (relative risk reduction [RRR] 32%, 95% CI –9% to 55%) or new or worsened back disability (RRR 15%, CI –15% to 37%) during follow up. After adjustment for new fractures during follow up, the effect of alendronate remained for the cumulative incidence of ≥7 days of bed rest; the incidence of limited activity days was similar between groups.

Conclusion
In postmenopausal women with osteoporosis and ≥1 existing vertebral fracture, alendronate reduced the days of bed rest and limited activity related to back pain.

In any event, this study shows that alendronate can reduce back pain in women.

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Alendronate v placebo in postmenopausal women with osteoporosis and ≥1 existing vertebral fracture

<table>
<thead>
<tr>
<th>Outcomes at 3 years</th>
<th>Cumulative incidence rate</th>
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<tbody>
<tr>
<td></td>
<td>Alendronate</td>
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<tr>
<td>≥1 day of bed rest</td>
<td>11%</td>
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<tr>
<td>≥7 days of bed rest</td>
<td>4%</td>
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<tr>
<td>≥7 days of limited activity</td>
<td>41%</td>
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</tbody>
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‡See glossary.