[2002] [FRI0297] ONCE WEEKLY ALENDRONATE PRODUCES A GREATER DECREASE IN BONE RESORPTION THAN DAILY RISEDRONATE

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Objectives: We report the results of the first head-to-head trial designed to compare the efficacy of alendronate and risedronate for the treatment of osteoporosis.

Methods: The 3-month, randomized, double-blind, multicenter international study enrolled 550 postmenopausal women, 60-90 year old (mean, 69), with osteoporosis defined by low BMD T-score (either lumbar spine or total hip/femoral neck <= -2.5, or <= -2.0 at both sites). The primary endpoint was 3-month change in urinary N-telopeptides of type 1 collagen/creatinine (NTx), a marker of bone resorption. Patients maintained a calcium intake of at least 1000 mg daily through food and/or calcium supplements. Patients were randomized into three treatment groups: alendronate 70mg once weekly using standard am. dosing; risedronate 5mg daily dosed 2 hours after a meal and at least 2 hr before the next; or matching placebo for each.

Results: Results are based on an intention-to-treat analysis of urinary NTx for the initial 351 patients completing Month 3.

Tests for between treatment comparison of alendronate vs risedronate, alendronate vs placebo, and risedronate vs placebo had p-values <0.001.

Table: Percent Change in Bone Resorption from Baseline at Month 3 ***:
p<=0.001: Within-treatment test of mean=0

<table>
<thead>
<tr>
<th></th>
<th>Placebo (N=69)</th>
<th>Alendronate (N=129)</th>
<th>Risedronate (N=139)</th>
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</thead>
<tbody>
<tr>
<td>Mean</td>
<td>-10.5</td>
<td>-55.1***</td>
<td>-36.0***</td>
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<tr>
<td>Mean ± SE</td>
<td>(-15.5, -5.2)</td>
<td>(-57.2, -52.9)</td>
<td>(-38.7, -33.1)</td>
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Conclusion: In this study, alendronate produced a 50% greater reduction in bone resorption than did risedronate. This difference may be due to the superior anti-resorptive efficacy of alendronate 70 mg once weekly, reduced bioavailability of risedronate resulting from post-meal dosing, or both.

Osteoporosis Clinical aspects and treatment