primary studies - published RCT

Autoantibodies against bactericidal/permeability-increasing protein (BPI-ANCA) in cystic fibrosis patients treated with azithromycin.

Code: PM16096858 **Year:** 2005 **Date:** 2008 **Author:** Rotschild M

Study design (if review, criteria of inclusion for studies)

Randomized, placebo-controlled trial.

Participants

56 adults randomised. Participants had CF confirmed by positive sweat test result or DNA acid analysis and a BMD T score of 1.0, as determined by dual-energy radiograph absorptiometry. Participants who had undergone organ transplantation; had endoscopy-proven oesophagitis, gastritis, and ulceration; had metabolic bone disorders; had severe renal disease; had used systemic corticosteroids (dose, 7.5 mg/d) or other drugs known to influence bone metabolism in the previous 6 months; or had osteomalacia and other documented contraindications were excluded from the study. Alendronate group: 27 randomised (17 males, 10 females) mean (SD) age 28.1 (7.7) years. 4 withdrew (2 non-compliance, 1 due to adverse event, 1 withdrew consent). 23 completed study. Placebo group: 29 randomised (17 males, 12 females) mean (SD) age 30.9 (9.7) years. 5 withdrew (2 non-compliance, 2 due to adverse event, 1 lost to follow-up). 24 completed study.

Interventions

Placebo or oral alendronate, 70 mg once weekly for 12 months. Medication was taken while sitting upright and with water only on an empty stomach at least 30 min before first food or beverage of the day. In addition, all participants received 800 IU of vitamin D and 1000 mg of calcium (500 mg supplementation, 500 mg from diet) daily.

Outcome measures

Compliance was measured through pill counts at each visit and patient self-report during telephone contact. In-clinic assessments at 6 and 12 months, and telephone follow-up was conducted by study staff at months 3 and 9. Clinic assessments at baseline and 12 months included a physical examination, vital signs, biochemistry (serum and urine) tests, pulmonary function tests (including FEV1 and FVC), the Medical Outcomes Study 36-item short form, radiographs of the thoracic and lumbar spine, and DXA. Adverse events and drug reactions reported spontaneously and responses elicited at each contact. Safety analyses included all vertebral fractures, osteoporosis-related fractures, adverse reactions, and abnormal findings that had been detected through laboratory tests and physical examinations. Documentation for all adverse events were blinded and adjudicated by the external Data Safety Monitoring Committee. All adverse events were reported regardless of attribution to study medication.

Main results

A total of 56 participants were enrolled in the study (mean age, 29.1 +/- 8.78 years; 61% male). The absolute percentage changes in lumbar spine and total hip BMDs at follow-up were significantly higher in the alendronate therapy group (5.20 +/- 3.67% and 2.14 +/- 3.32%, respectively) than those in the control group (- 0.08 +/- 3.93% and - 1.3 +/- 2.70%, respectively; p

Authors' conclusions

Alendronate therapy was well tolerated and produced a significantly greater increase in BMD over 12 months compared with placebo.

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See also

Clin Exp Med. 2005 Jul;5(2):80-5.

Keywords

Adult; Alendronate; Bone Density Conservation Agents; Bone Diseases; Drug Administration Schedule; Oral; Osteoporosis; pharmacological_intervention; prevention; Bisphosphonates;