primary studies - published RCT

Use of computerized tomography and chest x-rays in evaluating efficacy of aerosolized recombinant human DNase in cystic fibrosis patients younger than age 5 years: a preliminary study.

Code: PM11340684 **Year:** 2001 **Date:** 2004 **Author:** Nasr SZ

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

Randomised controlled trial; parallel design; double-blind placebo-controlled

Participants

Single centre, adult CF centre, USA. Inclusion criteria: CF, ambulatory, DXA showed a spine or femur T-score of -1 or less; Exclusion criteria: primary graft failure or other post-operative morbidities that precluded long-term survival, renal insufficiency (serum creatinine > 3.0 mg/dl), active upper gastrointestinal disease, chronic oral glucocorticoid usage (>10 mg every day) 101 participants consented to be screened, 86 qualified and 53 started protocol and were randomised. N = 48 (24 in treatment group); 23 females (9 in treatment group). Treatment group: mean (SD) age 28 years (7 years); control group: mean (SD) age 27 years (9 years). At baseline, osteoporosis was found in 3 participants and osteopenia was present in 20 participants in both the treatment and control group.

Interventions

Oral alendronate (10mg daily). All participants received oral vitamin D (800IU/day) and oral calcium carbonate (1000mg/day).

Outcome measures

Primary outcome: BMD (spine; 0, 6, 12, 18, 24 months; DXA Hologic QDR 1000/W Waltham MA) with 12 months data. Secondary outcomes: BMD (femur; 0, 6, 12, 18, 24 months; DXA Hologic QDR 1000/W Waltham MA); New fractures (number of fractures during study; long bone using clinical data, rib using posteroanterior chest radiographs, vertebral using lateral chest radiographs); Adverse events (number during study; fever, bone pain); Withdrawals; Survival. Serum (parathyroid hormone, 25-hydroxyvitamin D, 1,25-dihydroxyvitamin D, osteocalcin, bone-specific ALP) and urine (cross-linked N-telopeptides and deoxypyridinoline) biochemical measurements;

Main results

The alendronate-treated patients gained (mean +/- SD) 4.9 +/- 3.0% and 2.8 +/- 3.2% bone density after 1 year versus placebo, which lost (mean +/- SD) 1.8 +/- 4.0% and 0.7 +/- 4.7%, in spine and femur bone density, respectively (p

Authors' conclusions

Alendronate was more effective than placebo in improving spine and femur bone mineral density and is a promising agent for the long-term prevention and management of bone disease in patients with CF.

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See also

Pediatr Pulmonol. 2001 May;31(5):377-82.

Keywords

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