

primary studies - published RCT

Inhaled heparin in cystic fibrosis.

Code: PM16452592

Year: 2006 Date: 2009

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

Randomized, double-blind, placebo-controlled clinical trial.

Participants

Adult CF outpatient clinics at two hospitals. 22 non-transplanted CF patients aged \geq 18 years with a bone densitometry T-score of

Interventions

Participants were randomized to receive either 2 mg zoledronate i.v. (n = 10) or normal saline (placebo, n = 12) every 3 months for 2 years (8 infusions). All participants received calcium and vitamin D supplements twice daily.

Outcome measures

Percentage change in areal BMD from baseline.

Main results

Lumbar spine BMD increased from baseline more with zoledronate than placebo at 6 months (5.35 \pm 0.76 vs. 1.19 \pm 1.20%, P = 0.012), 12 months (6.6 \pm 1.5 vs. 0.35 \pm 1.55%, P = 0.011) and 24 months (6.14 \pm 1.86 vs. 0.44 \pm 0.10, P = 0.021). Femoral neck BMD increased more after zoledronate than placebo at 6 months (3.2 \pm 1.6 vs. -1.43 \pm 0.43%, P = 0.019), 12 months (4.12 \pm 1.8 vs. -1.59 \pm 1.4%, P = 0.024) and 24 months (4.23 \pm 1.3 vs. -2.5 \pm 1.41%, P = 0.0028). Forearm BMD did not change. Zoledronate was associated with flu-like and musculoskeletal side effects, particularly after the first infusion. There were no fractures in either group.

Authors' conclusions

Intravenous zoledronate was significantly more effective than placebo for increasing BMD in adults with CF and osteopaenia, but side effects limited its tolerability.

<http://dx.doi.org/10.1183/09031936.06.00069005>

See also

Eur Respir J. 2006 Feb;27(2):354-8.

Keywords

Adult; Bisphosphonates; Bone Density Conservation Agents; Bone Diseases; Intravenous; Osteoporosis; pharmacological_intervention; placebo; zoledronate;