primary studies - published RCT

Quality of life of children with cystic fibrosis.

Code: PM16202786 **Year:** 2005 **Date:** 2008 **Author:** Koscik RL

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

Double-blinded randomized cross-over trial with 4 arms. Single centre in USA.

Participants

15 CF children aged 7 to 13, remained on standard medication (including pancreatic enzymes and ADEK vitamins). Children on oral or glucocorticoids were excluded.

Interventions

4x6 month treatments (including placebo) with 3-month washout period between each. Placebo vs calcium (1g) vs vitamin D (1,600 IU) vs calcium (1g) plus vitamin D (1,600 IU)

Outcome measures

Blood and urine collected at beginning and end of each treatment. DXA performed at baseline, the beginning of each period and at 36 months (9 months between DXA - 6 month treatment plus washout). Calcium absorption at end of each period. Also, serum calcium, phosphorus, magnesium, parathyroid hormone, 25-hydroxyvitamin D, 1,25-dihydroxyvitamin D, osteocalcin, bone alkaline phosphatase, tartrate resistant acid phosphatase, urine calcium/creatinine ratio.

Main results

alpha was in the normal range and did not differ by treatment (P 35 +/- 10%, Ca 38 +/- 23%, D 36 +/- 11%, D + Ca 46 +/- 21%). One gram calcium did not increase serum or urine calcium. Two thousand IU D(3) did not increase 25-OHD or change 1,25(OH)(2)D. Serum and urine minerals, markers of bone turnover and bone mineral gains did not differ by treatment.

Authors' conclusions

alpha is normal in children with CF. One gram calcium and/or 2,000 IU D(3) does not change alpha or increase 25-OHD, serum calcium, or mineralization. Longer trials of a significantly higher dose of vitamin D(3) shown to increase serum 25-OHD are needed to assess effects on mineral metabolism and bone mass accrual. However, study of therapeutic options other than calcium and vitamin D should be encouraged.

http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/061/CN-00582061/frame.html

See also

J Pediatr. 2005 Sep;147(3 Suppl):S64-8.

Keywords

Adolescent; Bone Density Conservation Agents; Bone Diseases; Child; non pharmacological intervention - diet; pharmacological_intervention; Supplementation; Vitamin D; Vitamins;