

Cochrane Database of Systematic Reviews - - Cochrane Review

Cost-effectiveness of newborn screening for cystic fibrosis determined with real-life data

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Author: van der Ploeg CP

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

Randomised and quasi-randomised controlled trials of vitamin D supplementation compared to placebo in the CF population regardless of exocrine pancreatic function.

List of included studies (6)

Brown 2005; Hillman Deghan Manshadi 2012; Grossmann 2012; Haworth 2004; Hillman 2008; Sciuca 2011

Participants

Children or adults with CF (defined by sweat tests or genetic testing), with and without pancreatic insufficiency.

Interventions

Vitamin D

Outcome measures

Distal forearm bone mineral density (% change); Hip bone mineral density (% change); Lumbar spine bone mineral density (% change); Lumbar spine z score; Parathyroid hormone levels (change from baseline); Parathyroid hormone levels (pg/ml) (absolute); Serum calcium change (mmol/L); Vitamin D level (1, 25 (OH)₂ D) pg/ml; Vitamin D level (25-OHD) pg/ml; Whole body bone mineral content (% change)

Main results

Six studies (239 participants) are included, although only three studies provided data from 69 adults and children with cystic fibrosis for analysis. One study compared a single high dose of vitamin D (250,000 IU) to placebo at the time of hospital admission with a respiratory exacerbation in 30 pancreatic insufficient adults with cystic fibrosis. The second study compared supplemental 800 international units (IU) vitamin D and placebo for 12 months in 30 osteopenic pancreatic insufficient adults; both groups continued 900 IU vitamin D daily. The third study compared supplemental 1 g calcium alone, 1600 IU vitamin D alone, 1600 IU vitamin D and 1 g calcium and placebo in a double-blind randomised cross-over study; only nine children who completed both vitamin D and placebo groups after six-months supplementation and a three-month washout period are included; pancreatic sufficiency or disease status of participants are not defined. The studies are not directly comparable due to differences in supplementation, outcome reporting and possibly participant characteristics (e.g. severity of lung disease, growth and nutrition, pancreatic sufficiency). The only outcome for which we could combine data from more than two studies was 25-hydroxyvitamin D levels; patients receiving vitamin D supplementation had significantly higher levels, mean difference 7.24 ng/ml (95% confidence interval 5.01 to 9.46). However, ironically one study reported 1,25(OH)₂D with levels significantly favouring the placebo group, mean difference -30.30 pmol/ml (95% confidence interval -59.89 to -0.71). Bone mineral density was measured in two studies; both described no significant change between groups. There were no adverse events in any study. The remaining three studies are published as abstracts only and did not provide data for analysis. These abstracts include: a report of pre-intervention data in a study comparing daily calcitriol (0.25 or 0.5 micrograms) with placebo in pancreatic insufficient children and young adults; an interim report of a double-blind randomised control study comparing 5000 IU vitamin D daily for 12 weeks during winter in 67 adult cystic fibrosis patients; and a comparison of the effect of three months of vitamin D supplementation (dose not specified) with placebo on bone mineral density in 42 children with cystic fibrosis and low bone mineral density. Risk of bias was highly variable between all studies. Only one study had a low risk of bias for the five main criteria (random sequence generation, allocation, blinding, attrition and reporting). The rest of the studies had unclear or high risks of bias. Two studies had a low risk of bias for blinding and another two studies for attrition bias. In the studies published as abstracts, assessment of the risks of bias was uncertain in many aspects.

Authors' conclusions

In patients receiving vitamin D supplementation, 25-hydroxyvitamin D levels are significantly higher. However, there is no evidence of clinical benefit or harm in the limited number of small-sized published studies. Adherence to relevant cystic fibrosis guidelines on vitamin

D supplementation should be considered until further evidence is available.

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See also

J Cyst Fibros. 2014 Sep 8. pii: S1569-1993(14)00204-5.

Keywords

Adult; Bone Density Conservation Agents; Bone Diseases; Calcitriol; Child; Gastrointestinal Diseases; non pharmacological intervention - diet; Nutrition Disorders; Pancreas insufficiency; Pancreatic Diseases; pharmacological_intervention; Supplementation; vitamins; Vitamin D; Vitamin D Deficiency; Vitamin deficiencies; Vitamins; Malabsorption;