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[Intervention Review]

Vitamin E supplementation in people with cystic fibrosis

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ABSTRACT

Background

People with cystic fibrosis are at an increased risk of fat-soluble vitamin deficiency including vitamin E. Vitamin E deficiency can cause a host of conditions such as haemolytic anaemia, cerebellar ataxia and cognitive difficulties. Vitamin E supplementation is widely recommended in cystic fibrosis and aims to ameliorate this deficiency. This is an updated version of the review.

Objectives

To determine the effects of any level of vitamin E supplementation on the frequency of vitamin E deficiency disorders in people with cystic fibrosis.

Search methods

We searched the Cochrane Group's Cystic Fibrosis Trials Register and also searched international trial registers for any ongoing clinical trials that were not identified during our register search.

Date of last search of the Register: 10 October 2016.

Date of last search of international trial registers: 15 February 2017.

Selection criteria

Randomised controlled trials and quasi-randomised controlled trials comparing any preparation of vitamin E supplementation to placebo or no supplement, regardless of dosage or duration.

Data collection and analysis

Two authors extracted outcome data from each study (published information) and assessed the risk of bias of each included study.

Main results

Four studies with a total of 141 participants were included in the review, two of these were in children (aged six months to 14.5 years), and the other two did not specify participants' age. All studies used different formulations and doses of vitamin E for various durations of treatment (10 days to six months). Two studies compared the supplementation of fat-soluble as well as water-soluble formulations to no supplementation in different arms of the same study. A third study compared a water-soluble formulation to a placebo; and in the fourth study a fat-soluble formulation of vitamin E was assessed against placebo.

At one month, three months and six months, water-soluble vitamin E significantly improved serum vitamin E levels compared with control: at one month, two studies, mean difference 17.66 (95% confidence interval 10.59 to 24.74); at three months, one study, mean difference 11.61 (95% confidence interval 4.77 to 18.45); and at six months, one study, mean difference 19.74 (95% confidence interval 13.48 to 26.00). At one month fat-soluble vitamin E significantly improved serum vitamin E levels compared with control: one month, two studies, mean difference 13.59 (95% CI 9.52 to 17.66). The findings at three months were imprecise; one study; mean difference 6.40 (95% confidence interval -1.45 to 14.25).

None of the studies report the review's primary outcomes of vitamin E total lipid ratio or the incidence of vitamin E-specific deficiency disorders, or the secondary outcomes lung function or quality of life. Only one study, comparing water-soluble vitamin E with placebo, reported the secondary outcome of growth and nutritional status (weight), but the results are uncertain due to imprecision around the effect estimate.

There was limited detail about randomisation and blinding in the included studies which compromises the quality of the evidence base for the review. The heterogeneous mix of the formulations with differing biovailabilities among these studies also limits the generalisability of the data to the wider cystic fibrosis population.

Authors' conclusions

Vitamin E supplementation led to an improvement in vitamin E levels in people with cystic fibrosis, although the studies may have been at risk of bias. No data on other outcomes of interest were available to allow conclusions about any other benefits of this therapy.

In future, larger studies are needed, especially in people already being treated with enteric-coated pancreatic enzymes and supplemented with vitamin E, to look at more specific outcome measures such as vitamin E status, lung function and nutritional status. Future studies could also look at the optimal dose of vitamin E required to achieve maximal clinical effectiveness.

PLAIN LANGUAGE SUMMARY

Vitamin E supplementation in people with cystic fibrosis

Review question

We wanted to know what effects, if any, vitamin E supplementation (at any dose) has on how often people with cystic fibrosis have health problems due to vitamin E deficiency.

Background

Approximately 85% to 90% of people with cystic fibrosis do not produce enough enzymes in their pancreas and are not able to absorb fat when digesting food. These individuals are also likely to have problems absorbing the fat-soluble vitamins A, D, E and K. If levels of vitamin E are too low, this may cause problems with the nervous system, blood disorders and memory and thinking skills.

Search date

We last searched for evidence on 15 February 2017.

Study characteristics

The review identified four studies including 141 participants; two of these were in children (aged six months to 14.5 years) and the other two did not specify the age of the participants. The people taking part in the studies received different forms of vitamin E supplements (either water-soluble or fat-soluble), placebo (a substance containing no medication) or no supplements. Three studies stated that the treatment for each person was chosen at random, but one study only said the people were split into different groups.

Key results

Three of the studies showed an improvement in vitamin E levels after supplementation, but result should be interpreted with caution due to potential risks of bias. No studies reported any disorders related to vitamin E deficiency. As the studies used different forms of supplements and different doses, it was difficult to combine the results and apply them to the wider cystic fibrosis population, but the results did show that vitamin E supplementation can lead to an improvement in vitamin E levels in people with cystic fibrosis and may help avoid problems caused by vitamin E deficiency.

Future trials, especially in people already receiving treatment with pancreatic enzymes and vitamin E supplements, should look at more specific outcomes such as vitamin E status, lung function and nutritional status. They could also look at the best level of vitamin E supplements needed to be most clinically effective.

Quality of the evidence

We do not think that any of the people taking part in the studies could tell whether they received the supplements or the placebo, so that would not have affected the results; although they would have known if they were taking supplements or not taking anything. We could not tell from the information we have whether most of the studies were designed so all people had an equal chance of being in any of the groups. We also could not tell if anyone would have been able to guess in advance which group they would be in. It was also not clear if there were results reported for everyone taking part in the studies and the reasons why anyone might have dropped out of the studies. We do not know if these facts will affect our confidence in the results.