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Colistimethate sodium powder and tobramycin powder for inhalation for the treatment of chronic pseudomonas aeruginosa lung infection in cystic fibrosis: systematic review and economic model

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

Randomized controlled trials and quasi-randomised controlled trials.

List of included studies (4)

Harries 1969; Keljo 2000; Levin 1961; Wong 1988

Participants

All individuals with a diagnosis of CF who have not received a lung transplant. Since pancreatic insufficient (PI) and pancreatic sufficient (PS) patient groups are very different and are prescribed vitamin E supplements for very different reasons, studies with PI patients will be analysed separately from studies with PS patient groups

Interventions

Any preparation of vitamin E supplementation compared to placebo or no supplement

Outcome measures

Primary outcomes: vitamin E (total lipid ratio), vitamin E (levels in serum), incidence of vitamin E-specific deficiency disorders, peripheral neuropathy, retinopathy, myopathy and ataxia, cognitive impairment, haemolytic anemias

Main results

We included four studies, with a total of 401 randomised participants aged zero to seven years on enrolment; one study is ongoing. The two older included studies generally had a higher risk of bias across all domains, but in particular due to a lack of blinding and incomplete outcome data, than the two more recent studies. We only regarded the most recent study as being generally free of bias, although even here we were not certain of the effect of the per protocol analysis on the study results. Evidence quality was judged to be low for all outcomes assessed after being downgraded based on GRADE assessments. Downgrading decisions were due to limitations in study design (all outcomes), for imprecision and for inconsistency. Prophylactic anti-staphylococcal antibiotics probably make little or no difference to lung function measured as FEV1 % predicted after six years (mean difference (MD) $\hat{=}$ 2.30, 95% confidence interval (CI) $\hat{=}$ 13.59 to 8.99, one study, n = 119, low-quality evidence); but may reduce the number of children having one or more isolates of Staphylococcus aureus at two years (odds ratio (OR) 0.21, 95% CI 0.13 to 0.35, three studies, n = 315, low-quality evidence). At the same time point, there may be little or no effect on nutrition as reported using weight z score (MD 0.06, 95% CI $\hat{=}$ 0.33 to 0.45, two studies, n = 140, low-quality evidence), additional courses of antibiotics (OR 0.18, 95% CI 0.01 to 3.60, one study, n = 119, low-quality evidence) or adverse effects (low-quality evidence). There was no difference in the number of isolates of Pseudomonas aeruginosa between groups at two years (OR 0.74, 95% CI 0.45 to 1.23, three studies, n = 312, low-quality evidence), though there was a trend towards a lower cumulative isolation rate of Pseudomonas aeruginosa in the prophylaxis group at two and three years and towards a higher rate from four to six years. As the studies reviewed lasted six years or less, conclusions cannot be drawn about the long-term effects of prophylaxis.

Authors' conclusions

ger 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.

<http://www.journalslibrary.nihr.ac.uk/hta/volume-17/issue-56>

See also

Health Technol Assess. 2013 Dec;17(56):v-xvii, 1-181. doi: 10.3310/hta17560.

Keywords

Antioxidants; pharmacological_intervention; Supplementation; Vitamin E; Vitamins; non pharmacological intervention - diet;