

primary studies - published RCT

Studies of tocopherol deficiency in infants and children: VI. Evaluation of muscle strength and effect of tocopherol administration in children with cystic fibrosis.

Code: PM13761441

Year: 1961 **Date:** 1961

Author: Levin S

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

Randomized, placebo-controlled, double-blind study. Parallel design.

Participants

49 children attending the Fibrocystic Clinic at Babies Hospital (Columbia-Presbyterian Medical Center, New York) randomised. Diagnostic criteria not stated. Paper states " Only patients with a proven diagnosis of cystic fibrosis, and who were apparently stabilized on an accepted regimen of therapy, were accepted for the study." Patients had not previously received supplementary tocopherol. See note on withdrawals below, for final analysis 45 patients followed for at least 2 months, 37 patients completed 6 months of trial (18 in tocopherol group; 19 in placebo group).

Interventions

2 or 3 divided doses of 0.2 ml of mixture/kg/day. Supplement: 10 mg/dl alpha-tocopheryl acetate/kg/day. Placebo: further details not given.

Outcome measures

Weight, muscle strength, blood tests (tocopherol level; S-GOT), subjective rating of disease severity (scale of 1 - 5) by outcome assessors, estimate in change of disease status (scale 0 - 6) by outcome assessors after discussions with patients/carers.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/510/CN-00208510/frame.html>

See also

Pediatrics YR: 1961 VL: 27 DE: RCT

Keywords

Child; Infant; non pharmacological intervention - diet; Vitamin E; Vitamins; Antioxidants; pharmacological_intervention;