primary studies - published RCT

Randomized, double-blind, placebo-controlled pilot trial of megestrol acetate in malnourished children with cystic fibrosis.

Code: PM10997370 **Year:** 2000 **Date:** 2000 **Author:** Marchand V

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

randomized, placebo-controlled, double-blind, crossover study

Participants

12 children with CF

Interventions

megestrol acetate (MA) (10 mg/kg/d) or placebo for 12 weeks, followed by a 12-week washout period, then the alternative treatment.

Outcome measures

Anthropometrics, caloric intake, and clinical assessment were obtained every 6 weeks; pulmonary function tests, biochemistry, hematology, cortisol, growth hormone, insulin, C-peptide, insulin-like growth factor-1, insulin-like growth factor binding protein-3, and dual-energy x-ray absorptiometry scans were obtained every 12 weeks.

Main results

Six children did not complete the study, three for reasons unrelated to the study, two because they developed diabetes while receiving MA, and one who had glucose intolerance while receiving the placebo. Average weight gain was 3.05 kg in the MA group and 0.3 kg in the placebo group. The change in weight z score was +0.76 in the MA group and -0.05 in the placebo group. The change in height z score was -0.06 in the MA group and +0.06 in the placebo group. Lean body mass and body fat increased by 1507 g and 1192 g respectively in the MA group. Pulmonary function tests improved in the MA group; serum cortisol levels decreased. Side effects included glucosuria, insomnia, hyperactivity, and irritability.

Authors' conclusions

Weight, body fat, and lean body mass increased and pulmonary function improved in the children with CF given MA. Adrenal suppression, glucose intolerance, and diabetes are side effects.

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See also

J Pediatr Gastroenterol Nutr. 2000 Sep;31(3):264-9.

Keywords

Adolescent; Appetite Stimulants; Caloric Intake; Child; Hormones; Infant; megestrol; non pharmacological intervention - diet; Nutrition Disorders; pharmacological_intervention; placebo; Supplementation; Malnutrition;