primary studies - published RCT

A multicenter, randomized, double-blind, placebo-controlled trial to evaluate the metabolic and respiratory effects of growth hormone in children with cystic fibrosis.

Code: PM17545356 **Year:** 2007 **Date:** 2007 **Author:** Schnabel D

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

multicenter, randomized, placebo-controlled, double-blind study to assess the efficacy and safety

Participants

63 dystrophic patients with cystic fibrosis

Interventions

patients were randomly assigned for 24 weeks to 1 of 3 treatment arms: growth hormone dosage of 0.11 IU/kg body weight per day, growth hormone dosage of 0.21 IU/kg body weight per day, or placebo. The 24-week double-blind period was followed by an open treatment period of 24 weeks.

Outcome measures

The primary outcome measure was the change in forced expiratory volume in 1 second in percentage predicted from baseline. Secondary outcome measures were changes in height, weight, and exercise tolerance.

Main results

Height, growth velocity, and growth factors (insulin-like growth factor 1 and insulin-like growth factor-binding protein 3) increased significantly in both treatment groups, whereas weight gain did not differ between the growth hormone groups and placebo. A trend toward improvement in absolute forced vital capacity was observed in patients who received the higher growth hormone dosage, whereas forced expiratory volume in 1 second did not change significantly with growth hormone treatment. Maximal oxygen uptake during peak exercise increased significantly in treated patients. There were no significant differences in the frequency or severity of adverse effects or in the incidence of abnormalities in glucose metabolism.

Authors' conclusions

These data suggest that in the group investigated, growth hormone therapy was well tolerated and had positive metabolic effects but did not result in short-term improvement of lung function in patients with cystic fibrosis.

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See also

Pediatrics. 2007 Jun;119(6):e1230-8.

Keywords

Adolescent; Adult; Child; Growth Hormone; Hormones; pharmacological_intervention; placebo;