primary studies - published RCT

Prevention of chronic Pseudomonas aeruginosa colonisation in cystic fibrosis by early treatment.

Code: PM1679870 **Year:** 1991 **Date:** 1995 **Author:** Valerius NH

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

Double-blinded. Parallel study.

Participants

Multicentre (15 centres). CF diagnosed on clinical features and 2 raised sweat chloride (or sweat sodium) values. 285 participants recruited. Inclusion criteria: aged 6 - 14 years; clinical stability without hospitalisation for CF-related problems within 2 months of entry; serum IgG within 2 standard deviations of normal for centre or hypogammaglobulinaemia; reliable performance of lung functio Exclusion criteria included previous treatment with oral, inhaled or nasal corticosteroids for more than 2 weeks within 6 months of entry or any form of corticosteroids in previous month, evidence of liver disease, treatment with non-steroidal anti-inflam

Interventions

Prednisone 2 mg/kg or prednisone 1 mg/kg or placebo on alternate days (maximum dose 60 mg). Participants who missed 30% or more of total prescribed study medication were labelled as non-compliant but still included in analysis.

Outcome measures

Lung function was assessed at baseline and at 6, 12, 18, 24, 30, 36, 42 and 48 months. Primary outcomes were lung function (FEV1, FVC), serum IgG concentrations, growth and hospitalisation rates. Serum IgG was measured at baseline and at 3, 6, 12, 24, 36, 42 and 48 months. Height and weight were measured by techniques standardised across all participating centres. Height scores were calculated on the basis of age-stratified normal populations. Adverse events were monitored every 3 months with emphasis on raised blood glucose concentration, cataracts, raised liver enzymes and respiratory infection with unusual organisms (opportunistic infection). Growth was assessed in a 10-year follow-up study.

Main results

During the first 24 months the percentage of the predicted forced vital capacity was greater in the 1 mg/kg group (p

Authors' conclusions

Our These findings suggest a role for alternate-day prednisone therapy at a dose of 1 mg/kg in patients with mild to moderate cystic fibrosis. The benefit of improved lung function appears to outweigh the potential for adverse effects when the treatment period is less than 24 months.

http://dx.doi.org/10.1016/0140-6736(91)91446-2

See also

Lancet. 1991 Sep 21;338(8769):725-6.

Keywords

Adolescent; Bacterial Infections; Child; Drug Administration Schedule; Hospitalization; Hospital care; Immunization; Immunoglobulin G; Infection; pharmacological_intervention; Prednisolone; Prednisone; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Steroids; Immunoglobulins; Anti-Inflammatory Agents;