primary studies - published RCT

Alternate-day prednisone reduces morbidity and improves pulmonary function in cystic fibrosis.

Code: PM2863676 **Year:** 1985 **Date:** 1985 **Author:** Auerbach HS

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

Double-blinded. Randomised.

Participants

CF diagnosed on clinical features and raised sweat electrolytes. Mild to moderate pulmonary disease. 45 participants recruited aged 1 - 12 years. 24 assigned to placebo group and 21 to prednisone group. 11 participants did not complete study (7 placebo, 4 prednisone) - 2 moved cities, 5 excluded for non-compliance and steroids prescribed to 4 for clinical indications.

Interventions

Prednisone 2 mg/kg (maximum 60 mg) on alternate days or placebo.

Outcome measures

Liver function tests (aspartate aminotransferase, alkaline phosphatase, bilirubin and lactate dehydrogenase), glycosylated haemoglobin, circulating immune complexes, IgG, IgM, IgA, albumin, total protein, C3, C4, total white cell count, erythrocyte sedime The following were measured at baseline and 6 monthly: FEV1; FVC; PEFR. Height and weight measurements (not stated how frequently measured) expressed as percentage of mean height or weight for age from reference standards.

Main results

After 4 years, the prednisone-treated group had significant advantages over the placebo group for height, weight, vital capacity, forced expiratory volume in 1 s, peak flow rate, erythrocyte sedimentation rate, and serum IgG. The prednisone-treated group required 9 admissions to hospital for CF-related pulmonary disease compared with 35 for the placebo group. There were no steroid-induced side-effects. To rule out bias in case selection, 69 CF clinic patients comparable in age and clinical status but not included in the study were compared with the placebo group at 4 years; no significant differences between the groups were found.

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See also

Lancet. 1985 Sep 28;2(8457):686-8.

Keywords

Artificial Ventilation; Child; Drug Administration Schedule; Immunization; Immunoglobulin G; Infant; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Prednisolone; Prednisone; Steroids; Ventilators; Immunoglobulins; Anti-Inflammatory Agents;