primary studies - published RCT

A double-blind placebo controlled trial with oral ambroxol and N-acetylcysteine for mucolytic treatment in cystic fibrosis.

Code: PM3908111 **Year:** 1985 **Date:** 1985 **Author:** Ratjen F

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

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

Participants

Single centre in Germany. Age 6 - 21 years (mean 13.9). 36 participants with CF (16 male). Mild to moderate lung disease. Atopic individuals, and those on bronchodilators excluded.

Interventions

3 treatment arms. Oral NAC 200 mg tid, oral ABX 30 mg tid or placebo, each for 12 weeks.

Outcome measures

PFTs reported as mean values as percentage of normal, with no absolute values reported. PFTs (Raw, TGV, sRaw, REZ, VC, FEV1, FEV1/VC, V 75% FVC, V 50% FVC, V 25% FVC, PEF, TLC, RV/TLC) recorded after washout period, at 6 weeks and 12 weeks. After the study, parents and participants were asked whether they had improved, deteriorated or remained stable during the study, and if they thought that they had received a drug or placebo during the trial.

Main results

Although no clinical differences could be observed between the three groups, significant impairment in the placebo group was found for trapped air and FEV1 when compared to the active groups, suggesting a therapeutic effect of ambroxol and NAC in CF.

http://dx.doi.org/10.1007/BF00441781

See also

Eur J Pediatr. 1985 Nov;144(4):374-8.

Keywords

Acetylcysteine; Adolescent; Adult; Ambroxol; Bromhexine; Child; N Acetylcysteine; Oral; pharmacological_intervention; placebo; Airway clearance drugs -expectorants- mucolytic- mucociliary-; thiols; Respiratory System Agents; Mucosolvan; Nacystelyn;