primary studies - published RCT

A double-blind placebo-controlled trial of a pancreatic enzyme formulation (Panzytrat (R) 25 000) in the treatment of impaired lipid digestion in patients with cystic fibrosis.

Code: CN-00182417 **Year:** 1993 **Date:** 1997 **Author:** Chazalette JP

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

Double blind placebo controlled randomised sequence crossover trial.

Participants

Twenty three children from a regional cystic fibrosis centre were enrolled into the study, with mean age 10.3 years (range 7 to 17 years) and mean baseline forced expiratory volume in one second (FEV1) of 64% (range 21% to 102%) predicted for sex and height. One patient was excluded for non-compliance to the study protocol.

Interventions

Fluticasone propionate (400 micrograms/day) was given as a dry powder inhaler for six weeks with a four week washout period before crossover.

Outcome measures

Sputum inflammatory markers (interleukin-8, tumour necrosis factor-alpha (TNF-alpha) and neutrophil elastase-both free and bound to alpha 1-antiprotease), sputum interleukin-10, lung function, and symptomatology.

Main results

No significant benefit was shown for the use of fluticasone propionate in any of the outcomes. For sputum interleukin-8 there was an estimated true treatment median difference of 142 pg/ml (95% confidence interval (CI) 8 to 2866 pg/ml) in favour of placebo; while for maximal expiratory flow at 25% (MEF25%) remaining forced vital capacity predicted for sex and height there was a 15 percentage points (pp) (95% CI 4 to 26 pp) mean treatment difference in favour of placebo. Sputum interleukin-10 was undetected in any samples and unaffected by fluticasone propionate. Neither atopic status, baseline FEV1, nor concomitant DNase therapy had any effect on response to treatment.

Authors' conclusions

Lack of benefit from fluticasone propionate was most likely due to failure of the drug to penetrate the viscid mucus lining the airways. It is suggested a large multicentre trial with higher doses given for a longer time by a different delivery system is required to assess efficacy.

http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/417/CN-00182417/frame.html

See also

DRUG INVEST. YR: 1993 VL: 5 DE: RCT NO: 5

Keywords

Adolescent; Androstadienes; Anti-Inflammatory Agents; Child; fluticasone; Hormones; Inhalation OR nebulised; pharmacological_intervention; Steroids; Powders;