

primary studies - published RCT

Effect of inhaled azlocillin, mistabron and combination therapy in children with cystic fibrosis.

Code: CN-00208369 **Year:** 1985 **Date:** 1991

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

double-blind, crossover controlled trial

Participants

12 children with cystic fibrosis (CF) (seven males and five females) aged 7 to 17 yr (mean, 11.8 +/- 2.8)

Interventions

theophylline (T) or placebo (P) was taken for 10 days

Outcome measures

During Nights 9 and 10 of each study period, the subjects slept in a sleep laboratory, where complete polysomnographs were recorded.

Main results

Patients were subdivided according to T blood levels above or below 10 micrograms/ml: five children had a mean serum T of 11.7 +/- 1.6 micrograms/ml (Group 1), and seven patients had serum T levels of 6.7 +/- 1.5 micrograms/ml (Group 2). There was no difference in pulmonary function between the two periods, but Group 2 had significantly better baseline lung function (p less than 0.01). During sleep while on T, Group 1 had a higher mean SaO₂ (93.1 +/- 0.3% T versus 90.7 +/- 0.3% P; p less than 0.0001), less time with a decrease greater than 5% in SaO₂ from baseline (43.7 +/- 7.9 min T versus 85.8 +/- 7.9 min P; p less than 0.01), and a lower heart rate (HR), (77.9 +/- 5.1 bpm T versus 86.1 +/- 4.2 bpm P; p less than 0.01). Group 2 did not show differences in these parameters. T significantly disrupted sleep as measured by sleep efficiency and total wake time independently of serum level (p less than 0.01). There was no significant effect of T on the incidence of apnea, hypopnea, or body movements during sleep.

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See also

Pediatric Research YR: 1985 VL: 19 DE: RCT

Keywords

Bronchodilator Agents; Child; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Theophylline; Sleep Disorders; Chest physiotherapy; Aminophylline; Xanthines; Respiratory System Agents;