

primary studies - published RCT

Efficacy and safety of short-term administration of aerosolized recombinant human deoxyribonuclease in patients with cystic fibrosis.

Code: PM8317790

Year: 1993 **Date:** 1997

Author: Ramsey BW

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

Randomised, cross-over trial.

Participants

Six participants with CF and moderate to severe lung disease and significant gas exchange abnormalities during sleep. Stable participants. Mean (SD) age 22.3 (4.7) years (range 13 - 28 years). Mean (SD) FEV1% predicted 29.4 (3.4).

Interventions

Order of intervention was randomised. Three nights within a 15-day period. Session 1: Room air Session 2: Night-time low flow O2. Session 2: Night-time bilevel NIPPV with supplemental O2.

Outcome measures

TST; Sleep latency; NREM; NREM %TST; REM min; REM %TST; undetermined % TST; total arousals; arousal index; SaO2; TcCO2.

Main results

Compared to the control night, NIPPV and oxygen therapy significantly improved overall night-time oxygen saturation during both rapid eye movement (REM) and non-rapid eye movement (NREM) sleep stages. However, significant increases in transcutaneous CO2 tension occurred during oxygen therapy, while NIPPV markedly improved alveolar ventilation during all sleep states. Sleep architecture and arousals remained unchanged during NIPPV and oxygen therapy treatment nights.

Authors' conclusions

AB: Progressive deterioration of lung function in cystic fibrosis (CF) patients may lead to significant hypoxaemia and hypercapnia, especially during sleep. The effects of bi-level noninvasive positive pressure nasal mask ventilation (NIPPV) on respiration and sleep were compared to those of low-flow oxygen therapy in six CF patients (mean +/- SD age 22.3 +/- 4.7 yrs, with severe lung disease (forced expiratory volume in one second (FEV1) 29.4 +/- 3.4% predicted). Compared to the control night, NIPPV and oxygen therapy significantly improved overall night-time oxygen saturation during both rapid eye movement (REM) and non-rapid eye movement (NREM) sleep stages. However, significant increases in transcutaneous CO2 tension occurred during oxygen therapy, while NIPPV markedly improved alveolar ventilation during all sleep states. Sleep architecture and arousals remained unchanged during NIPPV and oxygen therapy treatment nights.

<http://www.ncbi.nlm.nih.gov/pubmed?term=Efficacy%20and%20safety%20of%20short-term%20administration%20of%20aerosolized%20recombinant%20human%20deoxyribonuclease%20in%20patients%20with%20cystic%20fibrosis>

See also

Am Rev Respir Dis. 1993 Jul;148(1):145-51.

Keywords

non pharmacological intervention - devices OR physiotherapy; non pharmacological intervention - diet; Oxygen; Supplementation; Ventilators;