primary studies - published RCT

Randomised placebo controlled trial of non-invasive ventilation for hypercapnia in cystic fibrosis.

Code: PM17675317 **Year:** 2008 **Date:** 2008 **Author:** Young AC

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

Randomised, cross-over trial.

Participants

8 participants with CF. Mean (SD) age 37 (8) years. Mean (SD) FEV1% predicted 35 (8). Mean (SD) BMI 21.1 (2.6) kg/m2. Mean (SD) PaCO2 52 (4) mmHg. Moderate and severe lung disease. No details on whether participants are in acute or stable state.

Interventions

Order of intervention was randomised with a 2-week washout period; 6 weeks of nocturnal air (placebo), oxygen and NIV.

Outcome measures

Post treatment assessments were carried out during a period of clinical stability i.e. no current need for hospitalisation or intravenous antibiotics. CF specific QoL questionnaire; daytime sleepiness; exertional dyspnoea; awake and asleep gas exchange; sleep architecture; lung function; peak exercise capacity. Neurocognitive function (PVT :mean; error; lapse); stroop color & word test; trail making test

Main results

Compared with air, NIV improved the chest symptom score in the CF QoL Questionnaire (mean difference 10; 95% CI 5 to 16; p = 0.002) and the transitional dyspnoea index score (mean difference 3.1; 95% CI 1.2-5.0; p = 0.01). It reduced maximum nocturnal pressure of transcutaneous CO2 (PtcCO2 mean difference -17 mm Hg; 95% CI -7 to -28 mm Hg; p = 0.005) and increased exercise performance on the Modified Shuttle Test (mean difference 83 m; 95% CI 21 to 144 m; p = 0.02). NIV did not improve sleep architecture, lung function or awake PaCO2.

Authors' conclusions

6 weeks of nocturnal NIV improves chest symptoms, exertional dyspnoea, nocturnal hypoventilation and peak exercise capacity in adult patients with stable CF with awake hypercapnia. Further studies are required to determine whether or not NIV can improve survival.

http://dx.doi.org/10.1136/thx.2007.082602

See also

Thorax. 2008 Jan;63(1):72-7. Epub 2007 Aug 3.

Keywords

Adult; exercise; non pharmacological intervention - devices OR physiotherapy; Oxygen; placebo; Sleep Disorders; Ventilators; Positive-Pressure Respiration- PEP- pep mask; Airway clearance technique;