primary studies - published RCT

Randomized Cross-Over Analysis of the Influence of Nitrogen Multiple Breath Washout on Spirometry in Monitoring Lung Function in Patients With Cystic Fibrosis and Primary Ciliary Dyskinesia.

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

Randomized Cross-Over Trial

Participants

Patients with Cystic Fibrosis (pwCF) and Primary Ciliary Dyskinesia (pwPCD). 47 clinically stable outpatients (36 pwCF, 11 pwPCD; 16.7â€‰Â±â€‰8.1 years)

Interventions

Each patient underwent N(2)MBW and spirometry at two consecutive visits (median interval 104 days): Group I: Spirometry followed by N(2)MBW (A), reversed order at the second visit (B), Group II reversed (Bâ†'A).

Outcome measures

z-score FEV1

Main results

There was a significant deterioration in z-score FEV1 between the two appointments (period effect: -0.177; pâ€‰=â€‰0.012). The intervention effect and 95% confidence interval were within the equivalence range in both groups (z-score FEV1: 0.039; -0.0765 to 0.1539, LCI(2.5): -0.082; -0.3691 to 0.2054).

Authors' conclusions

AB - BACKGROUND: When monitoring lung function in patients with Cystic Fibrosis (pwCF) and Primary Ciliary Dyskinesia (pwPCD), nitrogen multiple breath washout (N(2)MBW) is usually performed before spirometry to prevent forced expiratory maneuvers from altering N(2)MBW results. The N(2)MBW may affect spirometry if cooperation decreases after a long period of examination or due to prolonged oxygen inhalation. The equivalence of these concepts has never been investigated in a randomized cross-over trial. We hypothesized that the order of pulmonary function tests (PFTs) would not influence the z-score FEV(1). METHODS: A total of 47 clinically stable outpatients (36 pwCF, 11 pwPCD; 16.7â€‰Â±â€‰8.1 years) were randomized into two groups. Each patient underwent N(2)MBW and spirometry at two consecutive visits (median interval 104 days): Group I: Spirometry followed by N(2)MBW (A), reversed order at the second visit (B), Group II reversed (Bâ†'A). STATISTICS: For the equivalence test, a change in z-score FEV1 (primary endpoint) Â±0.2 and lung clearance index (LCI(2.5), secondary endpoint) Â±15% was not considered relevant; therefore, changes outside this range were considered an intervention effect in the linear mixed model (pâ€‰

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See also

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Keywords

non pharmacological intervention - devices OR physiotherapy; Exacerbation; Multiple Breath Washout; diagnostic procedures; non pharmacological intervention - diagn;