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Effects of a new airway clearance technology in children with cystic fibrosis - a homecare randomized controlled trial

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INTRODUCTION

This trial aims to evaluate the therapeutic effects of a new airway clearance technology (Simeox, Physio-Assist) added to optimal standard care (SC) including chest physiotherapy (CPT) at home in children with cystic fibrosis (CF).

METHODS

40 pediatric patients (8-17 years) with clinically stable CF were randomized 1:1 in a cross-over trial: SC with (device) or without (control) Simeox. All patients performed CPT x3/day + bronchodilators x2/day and were treated x2/day with Simeox in device group. After 1 month of therapy at home, patients switched on other study group for 1 additional month of therapy. Selected parameters of spirometry, body plethysmography (BP), impulse oscillometry system (IOS), lung clearance index (LCI), health-related quality of life (CFQ-R), side effects, tolerability, satisfaction were assessed during the study.

RESULTS

Baseline data: F/M 22/18, 13±3 y, BMI 19±3 kg/cm^2, FEV_1 91±18%, FVC 97±14%. No side effects occurred. IOS parameters did not change in both groups. Compared to baseline, LCI z-score remained stable in device group but worsened in control group (p=0.014). MEF75 z-score improved in device group versus control (+0.30, p=0.008), other spirometry and BP parameters did not change in both groups. Physical functioning domain score of CFQ-R was improved in device group only (+3.4 versus control, p=0.015), respiratory score was unchanged in both groups. There was no pain nor discomfort in 95% of patients, 78% felt no fatigue during session. 73% preferred Simeox to CPT and 95% would recommend it to other patients.

CONCLUSION

These results suggest that Simeox may improve drainage of central and peripheral airways in children with clinically stable CF and could be an option in chronic treatment of CF.

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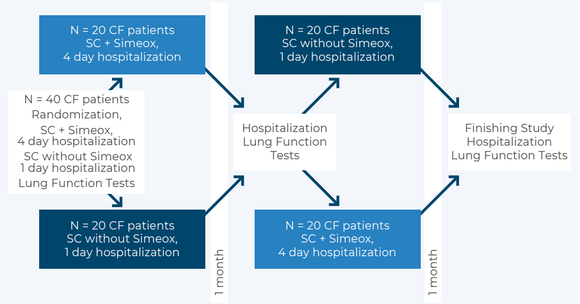
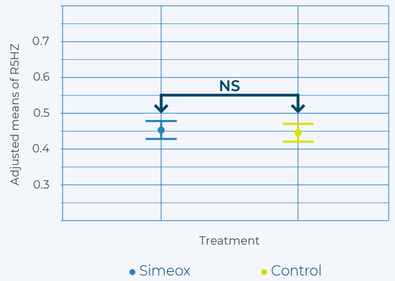
Effects of Simeox therapy in Children with stable CF
A Homecare cross-over RCT (NCT04084041)



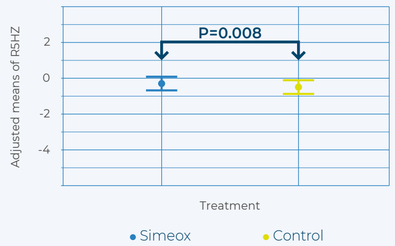
Baseline data

N=40	Mean±SD
Age (y)	13.0±2.8
Gender (F/M)	22/18 (55/45)
BMI (kg/m^2)	18.5±2.5
Pancreatic insufficiency	36 (90%)
Diabetes	15 (37.5%)
Sinus polyposis	26 (65%)
Cirrhosis	1 (2.5%)
Chronic Pseudomonas Aeruginosas	8 (20%)
FEV1% pred	90.9±17.5
FVC% pred	97.4±14.0
FEV1/FVC	81.1±9.4

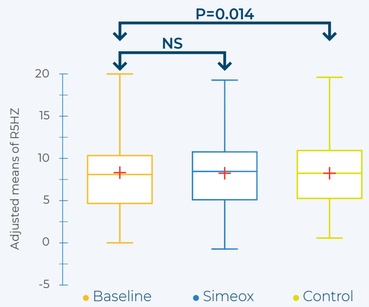
Adjusted means of R5HZ
according to treatment, with confidence intervals



MEF75 z-score
significantly improved in Simeox group by
+0.30 versus Control group (CI95%: 0.03;0.57, p=0.008)



LCI 2.5 z-score
according to treatment groups



CFQ-R physical functioning score
significantly improved in Simeox group by
+3.4 versus Conventional group (CI95%: 0.6;6.2, p=0.015)