primary studies - published RCT

Assessment of safety and efficacy of long-term treatment with combination lumacaftor and ivacaftor therapy in patients with cystic fibrosis homozygous for the F508del-CFTR mutation (PROGRESS): a phase 3, extension study.

Code: PM28011037 **Year:** 2016 **Date:** 2021 **Author:** Konstan MW

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

Randomised controlled single-centre interventional trial

Participants

21 paediatric CF patients with normal baseline spirometry.

Interventions

Reflex zone stimulation technique (RST). The effect of 30 minutes of RST was compared to that of sham therapy in a crossover design. The interventions were performed in random order and planned 6 months apart.

Outcome measures

The primary outcome was a change in global ventilation inhomogeneity after intervention, assessed by lung clearance index (LCI(2.5)) derived from a nitrogen multiple breath washout test. Secondary outcomes included changes in regional ventilation inhomogeneity (indices of acinar [Sacin*Vt] and conductive airway [Scond*Vt] inhomogeneity) and spirometry parameters (inspiratory capacity, forced vital capacity, and forced expiratory volume in 1 second). Trunk deformity was assessed by physiotherapists at study entry.

Main results

After the RST intervention, the LCI(2.5) (p = 0.004) and Scond*Vt (p = 0.009) decreased significantly, while inspiratory capacity increased (p = 0.012). In the sham-therapy group, none of the parameters changed significantly. Trunk deformity was seen in 76.5% of all patients, and 92.9% of those with trunk deformity showed a decrease in LCI(2.5) after RST.

Authors' conclusions

RST has multiple positive short-term effects on lung function, especially in CF patients with trunk deformities.

http://dx.doi.org/10.1016/S2213-2600(16)30427-1

See also

Lancet Respir Med. 2016 Dec 20. pii: S2213-2600(16)30427-1. doi: 10.1016/S2213-2600(16)30427-1.

Keywords

Reflex zone stimulation; non pharmacological intervention - devices OR physiotherapy;