

primary studies - published RCT

Efficacy and safety of lumacaftor and ivacaftor in patients aged 6-11 years with cystic fibrosis homozygous for F508del-CFTR: a randomised, placebo-controlled phase 3 trial.

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

Parallel arm multicenter randomized controlled trial

Participants

117 CF patients (40% of target sample size)

Interventions

Vigorous physical activity (PA). A 12-month partially supervised PA intervention using motivational feedback. The intervention group consented to add 3 hours of vigorous PA per week, while the control group was asked not to change their PA behavior.

Outcome measures

Primary endpoint was change in percent predicted forced expiratory volume in 1s (\hat{I}° FEV(1)) at 6 months. Secondary endpoints included PA, exercise capacity, exercise motives, time to first exacerbation and exacerbation rates, quality of life, anxiety, depression, and stress, and blood glucose control. Data were analyzed using mixed linear models.

Main results

117 patients (40% of target sample size) were randomized to an intervention (n=60) or control group (n=57). After 6 months, \hat{I}° FEV(1) was significantly higher in the control group compared to the intervention group (2.70% predicted, 95% CI 0.13 to 5.26; p=0.04). The intervention group reported increased vigorous PA compared with the control group at each study visit, had higher exercise capacity at 6 and 12 months, and higher PA at 12 months. No effects were seen in other secondary outcomes.

Authors' conclusions

ACTIVATE-CF increased vigorous PA and exercise capacity, with effects carried over for the subsequent 6 months, but resulted in better FEV(1) in the control group.

[http://dx.doi.org/10.1016/S2213-2600\(17\)30215-1](http://dx.doi.org/10.1016/S2213-2600(17)30215-1)

See also

Lancet Respir Med. 2017 Jun 8. pii: S2213-2600(17)30215-1. doi: 10.1016/S2213-2600(17)30215-1.

Keywords

Adolescent; Adult; Child; exercise; non pharmacological intervention - devices OR physiotherapy; Sports;