

primary studies - published RCT

# Empire-CF study: A phase 2 clinical trial of leukotriene A4 hydrolase inhibitor acebilustat in adult subjects with cystic fibrosis.

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

Non-blinded randomised controlled trial

## Participants

30 adults hospitalised with a CF exacerbation

## Interventions

Patients were allocated to an experimental intervention (Elx; MetaNeb) or a control intervention (Clx; their usual ACT). Both groups underwent twice-daily supervised airway clearance sessions, over an intervention period that ranged from 5 to 7 days during their hospitalisation.

## Outcome measures

The primary outcome was ventilation inhomogeneity measured via lung clearance index (LCI) using the multiple breath washout technique. Secondary outcomes included adverse events, respiratory mechanics, forced expiratory volumes, sputum inflammatory markers, wellness, expectorated sputum, symptoms, participant satisfaction, and huff and cough counts.

## Main results

Thirty participants were randomised (Elx group  $n=14$ ; Clx group  $n=16$ ). On completion of the intervention period, there was a greater improvement in LCI following the Elx than Clx (mean difference  $-0.84$  units  $[-1.66$  to  $-0.02]$ , as well as some measures of respiratory mechanics. There were no between-group differences for the other secondary outcomes.

## Authors' conclusions

In adults with CF who were hospitalised with an exacerbation, twice daily MetaNeb produced greater improvements in ventilation inhomogeneity compared to twice daily usual ACTs. There were no between-group differences shown for the other outcomes, including respiratory symptoms.

<http://dx.doi.org/10.1016/j.jcf.2021.08.007>

## See also

J Cyst Fibros. 2021 Sep 16:S1569-1993(21)01348-5. doi: 10.1016/j.jcf.2021.08.007.

## Keywords

nebuliser; non pharmacological intervention - devices OR physiotherapy; Exacerbation;