primary studies - published RCT

Safety, efficacy and convenience of tobramycin inhalation powder in cystic fibrosis patients: The EAGER trial.

Code: PM21075062 **Year:** 2011 **Date:** 2014 **Author:** Konstan MW

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

Multicenter, randomized, double-blind proof of concept study

Participants

70 CF subjects

Interventions

NAC or placebo orally thrice daily for 24weeks.

Outcome measures

Primary endpoint: change in sputum human neutrophil elastase (HNE) activity; secondary, FEV1 and other clinical lung function measures; and safety, the safety and tolerability of NAC and the potential of NAC to promote pulmonary hypertension in subjects with CF.

Main results

Lung function (FEV1 and FEF25-75%) remained stable or increased slightly in the NAC group but decreased in the placebo group (p=0.02 and 0.02). Log10 HNE activity remained equal between cohorts (difference 0.21, 95% CI -0.07 to 0.48, p=0.14).

Authors' conclusions

NAC recipients maintained their lung function while placebo recipients declined (24week FEV1 treatment effect=150mL, p

http://dx.doi.org/10.1016/j.jcf.2010.10.003

See also

J Cyst Fibros. 2011 Jan;10(1):54-61. Epub 2010 Nov 12.

Keywords

Acetylcysteine; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; N Acetylcysteine; pharmacological_intervention; Combined Modality Therapy; Oral; Respiratory System Agents; Nacystelyn;