primary studies - published RCT

A randomized placebo-controlled trial of miglustat in cystic fibrosis based on nasal potential difference.

Code: PM22281182 **Year:** 2012 **Date:** 2015 **Author:** Leonard A

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

RCT

Participants

41 children with CF aged 2-14 years, without chronic Pseudomonas infection

Interventions

Children were randomized to receive ciprofloxacin (n = 28) or placebo (n = 13) at the onset of acute viral respiratory infections on an intention to treat basis, during a study period of up to 32 months.

Outcome measures

adverse events, rate of withdrawal from the study, rate of Pseudomonas isolates

Main results

There were no unexpected adverse events believed related to the use of the study medication. The rate of withdrawal from the study was low (approximately 7%) and did not differ between groups. Randomization was effective and acceptable to participants. Primary and secondary outcome measures all favoured active treatment, but there were no significant between group differences. The median rate of Pseudomonas isolates was 0/patient/year (interquartile range 0-0.38) in both the active and placebo groups. Kaplan-Meier survival curves showed no significant difference in time to first Pseudomonas isolate between groups.

Authors' conclusions

This study demonstrated the clinical feasibility of using oral ciprofloxacin in CF patients at times of viral infection. Within this sample size, no significant association was found between active treatment and decreased growth of Pseudomonas in follow-up microbiological samples. A definitive study would require at least 320 children to demonstrate significant differences in the rate of pseudomonal isolates.

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See also

J Cyst Fibros. 2012 May;11(3):231-6. doi: 10.1016/j.jcf.2011.12.004. Epub 2012 Jan 27.

Keywords

Anti-Bacterial Agents; Ciprofloxacin; Intravenous; Oral; pharmacological_intervention; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Quinolones;