primary studies - published RCT

ALPINE2: Efficacy and safety of 14-day vs 28-day inhaled aztreonam for Pa eradication in children with cystic fibrosis.

Code: PM37455237 **Year:** 2024 **Date:** **Author:** Gilchrist FJ

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

Double-blind, phase 3b study

Participants

People with cystic fibrosis (pwCF) with newly isolated Pseudomonas aeruginosa (Pa). 149 participants were randomized and 142 (95.3%) completed treatment. Median age: 6.0 years (range: 0.3-17.0).

Interventions

Participants were randomized to receive 75 mg AZLI three times daily for either 28 or 14 days followed by 14 days' matched placebo.

Outcome measures

The primary endpoint was rate of primary Pa eradication (no Pa detected during the 4 weeks post AZLI treatment). Non-inferiority was achieved if the lower 95% CI bound of the treatment difference between the two arms was above -20%. Secondary endpoints included assessments of Pa recurrence during 108 weeks of follow-up after primary eradication. Safety endpoints included treatment-emergent adverse events (TEAEs).

Main results

In total, 149 participants were randomized (14-day AZLI, n = 74; 28-day AZLI, n = 75) and 142 (95.3%) completed treatment. Primary Pa eradication rates: 14-day AZLI, 55.9%; 28-day AZLI, 63.4%; treatment difference (CI), -8.0% (-24.6, 8.6%). Pa recurrence rates at follow-up end: 14-day AZLI, 54.1% (n = 20/37); 28-day AZLI, 41.9% (n = 18/43). TEAEs were similar between treatment arms. No new safety signals were observed.

Authors' conclusions

Non-inferiority of 14-day AZLI versus 28-day AZLI was not demonstrated. Both courses were well tolerated, further supporting AZLI short-term safety in paediatric and adolescent pwCF.

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See also

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Keywords

Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Colonization; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Monobactams;