ongoing trials - trial from other registries

Tolerability and Safety of Inhaled Colistimethate Sodium (CMS) Administered Once Daily Compared to Twice Daily Dosing in Adult and Adolescent Subjects with Cystic Fibrosis and Chronic Pseudomonas Aeruginosa Lung Infection (COPILOT) - Not yet recruiting

Code: ACTRN12624000601538 **Year:** 2024 **Date:** 2024 **Author:**

Participants

Adults with CF and two well-characterized genetic mutations in the CFTR gene, persistent airways PA infection

Interventions

Colistimethate Sodium (CMS) 4 MIU: vials of CMS 4 MIU (320 mg CMS) are reconstituted with 8 mL 0,9% saline solution, once daily, administered by inhalation via a nebuliser for 28 days

Outcome measures

Primary outcomes: number of observed safety events during the 28-day treatment period in each treatment arm[The tolerability and safety will be assessed based on all reported adverse events (ie dyspnoea, bronchoconstriction, cough, wheezing) , clinical laboratory test results, vital signs measurements, electrocardiogram findings, physical examination findings and spirometry results, or clinically significant changes thereof.

https://anzctr.org.au/ACTRN12624000601538.aspx

Keywords

Anti-Bacterial Agents; Bacterial Infections; colistimethate; Colistin; Infection; Inhalation OR nebulised; pharmacological_intervention; Powders; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; other anti-bacterial agents;