

ongoing trials - trial from other registries

A New Posaconazole Dosing Regimen for Paediatric Patients With Cystic Fibrosis and Aspergillus Infection - Phase 2|Phase 3 - Recruiting

Code: NCT04966234 **Year:** 2021 **Date:** 44309

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

Randomization: Not randomized, Blinding: Not blinded, Placebo: Not used, Assignment: Parallel, Purpose: Treatment.

Participants

Inclusion criteria: positive sputum culture with *Pseudomonas aeruginosa* The patient has the ability to excrete sputum The disease is in a stable condition (not in exacerbation) Forced expiratory volume(FEV1) is above 50%. have cystic fibrosis disease. Exclusion criteria: have hyper reactive airway disease. O2 saturation below 94%, in air room or when treated with oxygen. changes in cystic fibrosis drug over the past 4 weeks. have untreated reflux disease. Age minimum: 6 years Age maximum: 13 years

Interventions

Intervention 1: Intervention group: the usage of hypertonic saline 7% plus inhalation by a nebulizer ,twice a day for 2 months.drug Produced by Samen Pharmaceutical Company of Mashhad. Intervention 2: control group: the usage of hypertonic saline 7% inhalation by a nebulizer ,twice a day for 2 months.drug Produced by Samen Pharmaceutical Company of Mashhad.

Outcome measures

Forced expiratory volum in first second (FEV1). Timepoint: It is measured before prescribing the drug and then 2 months after prescribing the drug. Method of measurement: Spirometry. Forced vital capacity(FVC). Timepoint: It is measured before prescribing the drug and then 2 months after prescribing the drug. Method of measurement: Spirometry. LCI (Lung clearance index). Timepoint: It is measured before prescribing the drug and then 2 months after prescribing the drug. Method of measurement: Polmonary function test(LCI). Number of colony count of *pseudomonas aeruginosa*. Timepoint: It is measured before prescribing the drug and then 2 months after prescribing the drug. Method of measurement: Counting colonies after sputum culture. Quality of life. Timepoint: It is measured before prescribing the drug and then 2 months after prescribing the drug. Method of measurement: CFQ-R Questionnaire. Weight. Timepoint: It is measured before prescribing the drug and then 2 months after prescribing the drug. Method of measurement: scale.

<https://ClinicalTrials.gov/show/NCT04966234>

Keywords

hydration; Hypertonic Solutions; pharmacological_intervention; Inhalation OR nebulised; Oral; Respiratory System Agents;