ongoing trials - trial from other registries

Clinical trial of comparison between use of intravenous aminoglycosides versus intravenous and nebulize aminoglycosides in cystic fibrosis patients - Recruiting

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

Randomization: Randomized, Blinding: Triple blinded, Placebo: Used, Assignment: Parallel, Purpose: Treatment, Randomization description: The randomization has been performed using the permuted block randomization table. The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. In our study, subjects will be randomized in 4 patient blocks. Randomization was centralized and computerized with a concealed randomization sequence carried out at https://www.sealedenvelope.com/, Blinding description: The drug and placebo will be in coded same packages; a designated person will provide the codes from permuted block randomization via phone. The same person will group the data at the end of the trial, and the expert will perform statistical analysis and after results, the pocket that is with the placebo provider would be opened, and the data will be decrypted.

Participants

Inclusion criteria: cystic fibrosis flare up Exclusion criteria: chronic kidney disease hepatic failure metabolic disorder myopathy hearing loss neuromuscular disease electrolyte disturbances Age minimum: 6 years Age maximum: 18 years

Interventions

Intervention 1: Intervention group: Ceftazidime 50 milligrams per kg three times a day as intravenous, Amikacin 20 milligrams per kg one time a day as intravenous and Amikacin 500 milligrams as nebulize one time a day. Intervention 2: Control group: Ceftazidime 50 milligrams per kg three times a day as intravenous, Amikacin 20 milligrams per kg one time a day as intravenous and Normal saline as nebulize one time a day.

Outcome measures

Forced expiratory volume in the first second (FEV1). Timepoint: in baseline and 14 days after beginning of treatment. Method of measurement: Spirometer.

http://en.irct.ir/trial/55963

Keywords

Anti-Bacterial Agents; Bacterial Infections; Child; Infant; Infection; Inhalation OR nebulised; Intravenous; pharmacological_intervention; Pneumonia; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;