

ongoing trials - trial from other registries

Prospective validation and clinical evaluation of a new posaconazole dosing regimen for children and adolescents with cystic fibrosis and Aspergillus infection.

Code:
EUCTR2019-004511-31

Year: 2019 **Date:** 2019

Author:

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

Controlled: Yes.1 Randomised: Yes.2 Open: Yes.3 Single blind: No.4 Double blind: No.5 Parallel group: No.6 Cross over: No

Participants

Children and adolescents with CF and Aspergillus infection. Principal inclusion criteria: Inclusion criteria for the screening phase: 1. Diagnosed with cystic fibrosis (genetic diagnosis and/or abnormal sweat test and clinical phenotype of lung disease) - 2. Age \geq 8 yrs and

Interventions

Paediatric posaconazole dosing regimen

Outcome measures

Primary end point(s): - For the dosing algorithm: The number of children and adolescents with CF and Aspergillus infection aged 8 to 17 years reaching the pre-defined area under the concentration time curve (AUC) of posaconazole at the first assessment (between day 5 and 10) based on the adult reference concentrations for treatment of susceptible pathogens.

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-004511-31/GB/>

Keywords

Adolescent; Adult; Antifungal Agents; Child; pharmacological_intervention; Allergic Bronchopulmonary Aspergillosis -ABPA-; Aspergillus; Fungi; Infection; Respiratory Tract Infections; Respiratory Tract Diseases; posaconazole;