

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;