ongoing trials - trial from www.clinicaltrials.gov

A 4-week Study to Test Different Doses of BI 1265162 in Adolescents and Adults With Cystic Fibrosis Using the Respimat® Inhaler - Phase 2 - Not yet recruiting

Code: NCT04059094 **Year:** 2019 **Date:** September 2, 2019 **Author:** Boehringer Ingelheim

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

Interventional - Allocation: Randomized|Intervention Model: Parallel Assignment|Masking: Double (Participant, Investigator)|Primary Purpose: Treatment

Participants

Cystic Fibrosis - 12 Years and older (Child, Adult, Older Adult)

Interventions

Drug: BI 1265162|Drug: Placebo

Outcome measures

Efficacy of BI 1265162 is the change from baseline in percent predicted trough Forced Expiratory Volume in 1 Second (FEV1)|Change from baseline in Lung Clearance Index (LCI) assessed by N2 Multiple Breath Washout (N2MBW) procedure|Change from baseline in Cystic Fibrosis Questionnaire Revised (CFQ-R) total score|Change from baseline in Cough and Sputum Assessment Questionnaire (CASA-Q) (4 separate sub-scores)|Percentage of patients with treatment-emergent Adverse Events (AE)|Cmax,N (maximum measured concentration of the analyte in plasma following dose N)|Cpre,N (predose concentration measured for dose N)|AUC0-t,N (area under the concentration-time curve of the analyte in plasma until t hours after dose N)

https://ClinicalTrials.gov/show/NCT04059094

Keywords

Adult; Aged; Bronchodilator Agents; Child; pharmacological_intervention; placebo; tiotropium; Low-Dose; Anticholinergic Agents; Respiratory System Agents; nebuliser; non pharmacological intervention - devices OR physiotherapy; BI 1265162; ENaC antagonists - Sodium Channel Blocker;