ongoing trials - trial from www.clinicaltrials.gov

A Study to Test How Well BI 1291583 is Tolerated by People With Cystic Fibrosis Bronchiectasis (Clairaflyâ„¢) - Phase 2 - Not yet recruiting

Code: NCT05865886 **Year:** 2023 **Date:** October 16, 2023 **Author:** Boehringer Ingelheim

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

Interventional - Allocation: Randomized|Intervention Model: Parallel Assignment|Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)|Primary Purpose: Treatment

Participants

Cystic Fibrosis|Bronchiectasis - 18 Years and older (Adult, Older Adult)

Interventions

Drug: BI 1291583|Drug: Placebo

Outcome measures

Occurrence of Treatment emergent Adverse Events (TEAEs) up to 16 weeks from first drug administration|Relative change from baseline in neutrophil elastase (NE) activity in sputum at week 8 after first drug administration|Area under the concentration-time curve of the analyte in plasma over a uniform dosing interval (AUCÏ„) for the first dose|Maximum measured concentration of the analyte in plasma (Cmax) for the first dose|Area under the concentration-time curve of the analyte in plasma at steady state over a uniform dosing interval (AUCÏ„,ss)|Maximum measured concentration of the analyte in plasma (Cmax) at steady state (Cmax,ss)

https://ClinicalTrials.gov/show/NCT05865886

Keywords

BI 129158; Clairafly; Cathepsin C Inhibitor; Anti-Inflammatory Agents - excl Steroids; pharmacological_intervention;