

ongoing trials - trial from www.clinicaltrials.gov

A study to test how well BI 3720931 is tolerated and whether it improves lung function in people with cystic fibrosis (Lenticlair™ 1)

Code: CTIS-2023-503281-23-00 **Year:** 2023 **Date:** October 16, 2023

Author:

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 ($AUC_{0-\infty}$) for the first dose|Maximum measured concentration of the analyte in plasma (C_{max}) for the first dose|Area under the concentration-time curve of the analyte in plasma at steady state over a uniform dosing interval ($AUC_{0-\infty,ss}$)|Maximum measured concentration of the analyte in plasma (C_{max}) at steady state ($C_{max,ss}$)

https://trialssearch.who.int/Trial2.aspx?TrialID=CTIS2023-503281-23-00_2024

Keywords

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