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Proof-of-concept Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of SION-719 When Added to Trikafta

Code: NCT07108153 **Year:** 2025 **Date:** 04/06/2024

Author:

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

INTERVENTIONAL - Allocation: RANDOMIZED|Intervention Model: CROSSOVER|Masking: QUADRUPLE (PARTICIPANT, CARE_PROVIDER, INVESTIGATOR, OUTCOMES_ASSESSOR)|Primary Purpose: TREATMENT

Participants

Cystic Fibrosis - ADULT, OLDER_ADULT

Interventions

DRUG: Diponecaftor|DRUG: Placebo

Outcome measures

Mean percent predicted forced expiratory volume in 1 second (ppFEV1), The primary endpoint in both groups is the mean percent predicted forced expiratory volume in 1 second (ppFEV1) of measurements taken after 4, 6 and 8 weeks of treatment. Period baseline values will be corrected for in the analysis., Measurements taken at 4, 6 and 8 weeks of treatment

<https://clinicaltrials.gov/study/NCT07108153>

Keywords

Dirocaftor; PTI-808; CFTR Modulators; pharmacological_intervention; Posenacaftor; PTI-801; Nesolicaftor; PTI-428;