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A Study to Evaluate the Safety and Efficacy of VX-121 Combination Therapy in Subjects With Cystic Fibrosis - Phase 2 - Not yet recruiting

Code: NCT03912233 **Year:** 2019 **Date:** May 2019 **Author:** Vertex Pharmaceuticals Incorporated

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

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

Participants

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

Interventions

Drug: VX-121|Drug: TEZ|Drug: VX-561|Drug: TEZ/IVA|Drug: IVA|Drug: Placebo

Outcome measures

Safety and tolerability as assessed by number of subjects with adverse events (AEs) and serious adverse events (SAEs)|Absolute change in percent predicted forced expiratory volume in 1 second (ppFEV1)|Absolute change in sweat chloride concentrations|Absolute change in Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score|Maximum observed concentration (Cmax) of VX-121, TEZ, VX-561, IVA (Part 2), and relevant metabolites|Area under the concentration versus time curve during a dosing interval (AUCtau) of VX-121, TEZ, VX-561, IVA (Part 2), and relevant metabolites|Observed pre-dose concentration (Ctrough) of VX-121, TEZ, VX-561, IVA (Part 2), and relevant metabolites

https://ClinicalTrials.gov/show/NCT03912233

Keywords

Adult; Aged; CFTR Modulators; Genetic Predisposition to Disease; pharmacological_intervention; placebo; VX-121; Aminophenols; tezacaftor;