ongoing trials - trial from www.clinicaltrials.gov

A Phase 2 Study to Evaluate Efficacy and Safety of VX-561 in Subjects Aged 18 Years and Older With Cystic Fibrosis - Phase 2 - Not yet recruiting

Code: NCT03911713 **Year:** 2019 **Date:** 2019 **Author:** Vertex Pharmaceuticals Incorporated

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 - 18 Years and older (Adult, Older Adult)

Interventions

Drug: VX-561|Drug: IVA|Drug: Placebo

Outcome measures

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

https://ClinicalTrials.gov/show/NCT03911713

Keywords

Adult; Aged; CFTR Modulators; Genetic Predisposition to Disease; pharmacological_intervention; placebo; VX-561; Aminophenols; tezacaftor;