ongoing trials - trial from www.clinicaltrials.gov

A Phase 3 Study of VX-445 Combination Therapy in Cystic Fibrosis (CF) Subjects Heterozygous for F508del and a Gating or Residual Function Mutation (F/G and F/RF Genotypes) - Phase 3 - Not yet recruiting

Code: NCT04058353 **Year:** 2019 **Date:** August 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 - 12 Years and older (Child, Adult, Older Adult)

Interventions

Drug: ELX/TEZ/IVA|Drug: IVA|Drug: TEZ/IVA

Outcome measures

Absolute change in percent predicted forced expiratory volume in 1 second (ppFEV1) for ELX/TEZ/IVA group|Absolute change in sweat chloride (SwCl) for ELX/TEZ/IVA group|Absolute change in ppFEV1 for ELX/TEZ/IVA group compared to the control group|Absolute change in SwCl for ELX/TEZ/IVA group compared to the control group|Absolute change from baseline in Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score for ELX/TEZ/IVA group|Absolute change in CFQ-R respiratory domain score for ELX/TEZ/IVA group compared to the control group|Safety and tolerability as assessed by number of subjects with adverse events (AEs) and serious adverse events (SAEs)

https://ClinicalTrials.gov/show/NCT04058353

Keywords

Adult; Aged; CFTR Modulators; Genetic Predisposition to Disease; pharmacological_intervention; placebo; VX-770; VX-661; ivacaftor; Aminophenols; tezacaftor; VX-445; elexacaftor; Trikafta;