ongoing trials - trial from www.clinicaltrials.gov

Evaluation of Efficacy and Safety of Elexacaftor/Tezacaftor/Ivacaftor (ELX/TEZ/IVA) in Cystic Fibrosis Subjects Without an F508del Mutation - Phase 3 - Not yet recruiting

Code: NCT05274269 **Year:** 2022 **Date:** March 2022 **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 - 6 Years and older (Child, Adult, Older Adult)

Interventions

Drug: ELX/TEZ/IVA|Drug: IVA|Other: Placebo (matched to ELX/TEZ/IVA)|Other: Placebo (matched to IVA)

Outcome measures

Absolute Change in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)|Absolute Change in Sweat Chloride (SwCl)|Absolute Change in Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain (RD) Score|Absolute Change in Body Mass Index (BMI)|Absolute Change in Weight|Number of Pulmonary Exacerbations (PEx)|Safety and Tolerability as Assessed by Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)

https://ClinicalTrials.gov/show/NCT05274269

Keywords

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