ongoing trials - trial from other registries

A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-121 Combination Therapy in Subjects With Cystic Fibrosis Who Are Homozygous for F508del, Heterozygous for F508del and a Gating (F/G) or Residual Function (F/RF) Mutation, or Have At Least 1 Other Triple Combination Responsive CFTR Mutation and No F508del Mutation

Code: EUCTR2021-000694-85 **Year:** 2021 **Date:** 2021 **Author:**

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

Controlled: No.1 Randomised: No.2 Open: Yes.3 Single blind: No.4 Double blind: No.5 Parallel group: No.6 Cross over: No

Participants

Principal inclusion criteria: 1.Subject (or his or her legally appointed and authorized representative) will sign and date an informed consent form (ICF), and, when appropriate, an assent form.

Interventions

Main objective of the trial: To evaluate the effects of ELX/TEZ/IVA on cough and physical activity using wearable technology

Outcome measures

Primary end point(s): Percent reduction from baseline in cough frequency (cough events per day) to the average of Week 8 through Week 12

https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-000694-85/SE/

Keywords

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