ongoing trials - trial from other registries

A Phase 3b Open-label Study Evaluating the Effects of Elexacaftor/Tezacaftor/Ivacaftor on Cough and Physical Activity in Cystic Fibrosis Subjects 12 Years of Age and Older Who Are Heterozygous for the F508delMutation and a Minimal Function Mutation (F/MF)

Code: EUCTR2021-001628-16 **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/2021-001628-16/ES/

Keywords

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