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

Participants

Subjects aged 12 years or older, on the date of informed consent; Confirmed diagnosis of CF as determined by the investigator. Subject has one of the following genotypes: 1) homozygous for F508del; 2) heterozygous for F508del and a gating (F/G) mutation; 3) heterozygous for F508del and a residual function (F/RF) mutation; at least 1 other TCR CFTR mutation identified as responsive to ELX/TEZ/IVA and no F508del mutation. For subjects currently receiving Vertex CFTR modulator therapy, FEV1 value â‰¥40% and â‰¤90% of predicted mean for age, sex, and height at the Screening Visit. All subjects not currently receiving Vertex CFTR modulator therapy must have an FEV1 value â‰¥40% and â‰¤80% of predicted mean. Stable CF disease as judged by the investigator.

Interventions

VX-121/TEZ/D-IVA

Outcome measures

Primary end point(s): Absolute change from baseline in percent predicted forced expiratory volume in 1 second (ppFEV1) through Week 24.

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

Keywords

CFTR Modulators; Genetic Predisposition to Disease; pharmacological_intervention; placebo; VX-770; VX-121; ivacaftor; Aminophenols; tezacaftor; VX-661; vanzacaftor;