*ongoing trials - trial from other registries*

# A Phase 3b Open-label Study to Assess the Effect of Elexacaftor/Tezacaftor/Ivacaftor on Glucose Tolerance in Cystic Fibrosis Subjects with Abnormal Glucose Metabolism

**Code:** EUCTR2020-003170-44 **Year:** 2020 **Date:** 2020 **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

3. Subjects (male and female) 12 years of age or older on the date of informed consent.4. Subjects heterozygous for F508del and an MF mutation (F/MF genotypes).5. Forced expiratory volume in 1 second (FEV1) value .30% of predicted mean for age, sex, and height (equations of the Global Lung Function Initiative [GLI])9 at the Screening Visit (spirometry measurements must meet American Thoracic Society/European Respiratory Society criteria10 for acceptability and repeatability) and stable CF disease as judged by the investigator.

### Interventions

Main objective of the trial: To evaluate the effect of elexacaftor (ELX)/tezacaftor (TEZ)/ivacaftor (IVA) on glucose tolerance in CF subjects with impaired glucose tolerance (IGT) or CF-related diabetes (CFRD)

### Outcome measures

Primary end point(s): Change from baseline in 2-hour blood glucose levels following an oral glucose tolerance test

https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-003170-44/BE/

### Keywords

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