primary studies - published RCT

Impact of Elexacaftor/Tezacaftor/Ivacaftor on Glucose Tolerance and Abnormal Glucose Metabolism: A Phase 3b, Open-Label Clinical Trial.

Code: PM40788823 **Year:** 2025 **Date:** **Author:** Durieu I

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

Phase 3b, open-label study

Participants

â‰¥12 years of age, heterozygous for F508del and a minimal function CFTR mutation, with either IGT or CFRD

Interventions

Elexacaftor (ELX)/tezacaftor (TEZ)/ivacaftor (IVA) 48 weeks

Outcome measures

The primary endpoint was change in blood glucose concentration after a 2-hour oral glucose tolerance test from baseline to the average of Week 36 and Week 48. Secondary endpoints were the proportion of participants with improvement in dysglycemia categorization (CFRD, IGT, normal glucose tolerance) at Week 48 and safety.

Main results

Participants had a mean change of -35.0 mg/dl (95% confidence interval [CI], -49.2 to -20.7 mg/dl; Pâ€‰

Authors' conclusions

ELX/TEZ/IVA treatment led to clinically meaningful improvements in blood glucose regulation, with significant within-group decreases in blood glucose concentrations after oral glucose tolerance testing and improved dysglycemia categorization in people with CF with early IGT or CFRD.

http://dx.doi.org/10.1164/rccm.202411-2312OC

See also

Am J Respir Crit Care Med. 2025 Oct;211(10):1926-1934. doi: 10.1164/rccm.202411-2312OC.

Keywords

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