

primary studies - published, non RCT

# **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:** 1996

**Author:**

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

Interventional study, non randomized

## **Participants**

15 patients with cystic fibrosis, aged 13 to 35 years, who had mild to moderate airway obstruction.

## **Interventions**

Two different inspiratory maneuvers. Patients performed a forced expiratory maneuver either after a rapid inspiration without an end-inspiratory pause or after a slow inspiration with a 4-s end-inspiratory pause.

## **Outcome measures**

Flow-time and volume-time curves were measured by a pneumotachograph. Mean values of FVC, FEV1, and peak expiratory flow

## **Main results**

The mean values of FVC, FEV1, and peak expiratory flow were significantly larger by 11%, 13%, and 26%, respectively, after the rapid inspiration without an end-inspiratory pause compared to the slow inspiration with the end-inspiratory pause. This discrepancy probably reflects differences in effective elastic recoil pressure between the two maneuvers. Although the nature of this phenomenon is not fully understood, our results show that for spirometry in patients with cystic fibrosis, the preceding inspiratory maneuver influences the results. An important corollary is that this inspiratory maneuver should be standardized.

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-001628-16/ES/>

## **Keywords**

Adolescent; Adult; non pharmacological intervention - devices OR physiotherapy;