primary studies - published RCT

Effect of ivacaftor treatment in patients with cystic fibrosis and the G551D-CFTR mutation: Patient-reported outcomes in the STRIVE randomized, controlled trial.

Code: PM26135562 **Year:** 2015 **Date:** 2020 **Author:** Quittner A

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

Randomized, multi-center, double-blind, placebo-controlled, parallel-group trial

Participants

161 patients â‰¥12 years with a confirmed diagnosis of CF

Interventions

Patients were randomized to either placebo (saline) or active drug in 3 different dosing schemes of 2.5mg inhaled lancovutide (once daily, every other day or twice a week) for eight weeks.

Outcome measures

The primary endpoint was the change in the forced expiratory volume in 1 second (FEV1) percent predicted. Secondary endpoints included further lung function parameters (FEV1 (absolute), functional vital capacity percent predicted, forced expiratory flow percent predicted, pulse oximetry), quality of life assessment, pulmonary exacerbations, hospitalization due to pulmonary exacerbations, time to first pulmonary exacerbation, duration of anti-inflammatory, mucolytic or antibiotic treatment, and safety.

Main results

There was no significant difference in the change in FEV1 percent predicted, quality of life, other lung function parameters, pulmonary exacerbations or requirement of additional treatment between groups. Overall, the inhalation of lancovutide was safe although a higher rate of adverse events, especially related to the respiratory system, occurred as compared to placebo.

Authors' conclusions

Lancovutide did not improve FEV1 percent predicted when compared to placebo

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See also

Health Qual Life Outcomes. 2015 Jul 2;13:93. doi: 10.1186/s12955-015-0293-6.

Keywords

Adolescent; Adult; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; Moli1901; pharmacological_intervention; Respiratory System Agents; Lancovutide;