

primary studies - published RCT

## **Elexacaftor-Tezacaftor-Ivacaftor for Cystic Fibrosis with a Single Phe508del Allele.**

**Code:** PM31697873

**Year:** 2019 **Date:**

**Author:** Middleton PG

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

Secondary analysis of a multicenter, double-blind, randomized, placebo-controlled study.

### **Participants**

Adults with CF hospitalized for an acute pulmonary exacerbation (APE).

### **Interventions**

A high-dose bolus of cholecalciferol (vitamin D (3)). Within 72 hours of hospital admission, participants were randomly assigned to a single dose of oral vitamin D (3) (250,000 IU) or placebo, and subsequently, received 50,000 IU of vitamin D (3) or placebo every other week, beginning at month 3 and ending on month 12.

### **Outcome measures**

Glycemic control was assessed by hemoglobin A1c (HbA1c) and fasting blood glucose levels before and 12 months after the study intervention.

### **Main results**

Fifty of the 91 participants in the parent study were eligible for the secondary analysis. There were no differences in 12-month changes in HbA1c or fasting blood glucose in patients randomized to vitamin D or placebo.

### **Authors' conclusions**

A high-dose bolus of vitamin D (3) followed by maintenance vitamin D (3) supplementation did not improve glycemic control in patients with CF.

<http://dx.doi.org/10.1056/NEJMoa1908639>

### **See also**

N Engl J Med. 2019 Nov 7;381(19):1809-1819. doi: 10.1056/NEJMoa1908639. Epub 2019 Oct 31.

### **Keywords**

Adult; Bone Density Conservation Agents; Bone Diseases; Calcitriol; Child; Gastrointestinal Diseases; non pharmacological intervention - diet; Nutrition Disorders; Pancreas insufficiency; Pancreatic Diseases; pharmacological\_intervention; Supplementation; vitamins; Vitamin D; Vitamin D Deficiency; Vitamin deficiencies; Vitamins; Malabsorption;