

primary studies - published RCT

# **Sinonasal inhalation of dornase alfa administered by vibrating aerosol to cystic fibrosis patients: A double-blind placebo-controlled cross-over trial.**

**Code:** PM24594542

**Year:** 2014 **Date:** 2018

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

Multicentre, open-label, comparative, randomised trial

## **Participants**

49 centres in Austria, France, Germany, and Italy. Eligible patients had cystic fibrosis, were older than 10 years, and had newly diagnosed diabetes.

## **Interventions**

Insulin or repaglinide, stratified by sex and age (10-15 years or >15 years). 34 patients in the repaglinide group and 41 in the insulin group

## **Outcome measures**

The primary outcome was glycaemic control assessed by mean change in HbA1c concentration from baseline after 24 months of treatment. Differences between groups were assessed by linear models.

## **Main results**

At 24 months, glycaemic control was similar in the repaglinide and insulin groups (mean change in HbA1c concentration from baseline 0.2% [SD 0.7%], 1.7 mmol/mol [8.1 mmol/mol] with repaglinide vs -0.2% [1.3%], -2.7 mmol/mol, [14.5 mmol/mol] with insulin; mean difference between groups -0.4%, (95% CI -1.1 to 0.2 [-4.4 mmol/mol, -11.5 to 2.7],  $p=0.15$ ). The most frequent adverse events were pulmonary events (43 [40%] of 107 in the repaglinide group and 60 [45%] of 133 in the insulin group), and the most frequent serious adverse events were pulmonary events leading to hospital admission (five [50%] of ten and seven [54%] of 13, respectively).

## **Authors' conclusions**

Repaglinide for glycaemic control in patients with cystic-fibrosis-related diabetes is as efficacious and safe as insulin.

<http://dx.doi.org/10.1016/j.jcf.2014.02.005>

## **See also**

J Cyst Fibros. 2014 Mar 1. pii: S1569-1993(14)00045-9. doi: 10.1016/j.jcf.2014.02.005.

## **Keywords**

Adult; Aged; Child; Diabetes Mellitus; Gastrointestinal Diseases; Hypoglycemic Agents; Insulin; Pancreatic Diseases; pharmacological\_intervention; Repaglinide;