



# Cystic Fibrosis Research News

## Title:

LONG-TERM SAFETY STUDY OF COLISTIMETHATE SODIUM (COLOBREATHE®): FINDINGS FROM THE UK CYSTIC FIBROSIS REGISTRY

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## What was your research question?

The purpose of the study was to determine if the drug Colobreathe is safe for long term use by people with cystic fibrosis who have developed a chronic lung infection with the bacterium *Pseudomonas*.

## Why is this important?

While the safety of Colobreathe has been examined in clinical trials before it was approved, these clinical trials are usually short term and have strict rules on who can participate, how the product is used, and which other drugs can be taken during the study. People with cystic fibrosis should take this type of medicine for a long time and with other drugs. It is therefore important to examine the safety of Colobreathe in real life.

## What did you do?

We studied data from 4969 people with cystic fibrosis in the UK Cystic Fibrosis Registry over five years, from 2014-2018. We compared the occurrence of certain side effects, including coughing up blood and cough induced rib fracture, between a group of people taking Colobreathe and a group of people taking other inhaled antibiotics. We also looked at the reasons people stopped taking their antibiotics. To make the groups as similar as possible, in terms of people's characteristics and important measurements that may determine which antibiotic they are given, we used a statistical method called "matching".



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## **What did you find?**

People who took Colobreathe and those who took other inhaled antibiotics reported similar occurrences of side effects, similar occurrences of lung exacerbations, and similar reasons for stopping these medications.

## **What does this mean and reasons for caution?**

The safety profile of Colobreathe is similar to that of other inhaled antibiotics, supporting its long-term safety in people with cystic fibrosis. This study showed that the UK Cystic Fibrosis Registry is very useful for conducting long-term studies to determine drug safety.

This was an observational study (i.e., study with data collection from real-world setting with no intervention). Although we used established statistical methods to carefully match the two groups of people (those taking Colobreathe and those not taking Colobreathe), it is difficult to determine if all important differences between the groups were fully accounted for.

## **What next?**

The UK Cystic Fibrosis Registry will continue working with the European Medicines Agency and other cystic fibrosis registries in monitoring newly licensed drugs for people with cystic fibrosis.

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