

# Cystic Fibrosis Research News

## Title:

A Study to Test the Effects of a Treatment Called Amikacin Liposome Inhalation Suspension on Chronic *Pseudomonas aeruginosa* Infection in People with Cystic Fibrosis

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## What was your research question?

Does an inhaled (breathed in) antibiotic called ALIS (amikacin liposome inhalation suspension) work as well as another inhaled antibiotic (tobramycin inhalation solution, or TIS) to treat lung infection caused by the bacterium *Pseudomonas aeruginosa* (PA) in people with cystic fibrosis (CF)?

## Why is this important?

Many people with CF have lung infections that don't get better even after they take antibiotics. People with CF often take antibiotics that they breathe into their lungs. Lung infections caused by PA are hard to cure because many antibiotics can't kill PA or can't get deep enough into the lungs to fight the bacteria. Sometimes people do not respond to certain

# Cystic Fibrosis Research News

antibiotics or are unable to tolerate them. Studies help doctors understand how safe different antibiotics are and how well they work in people with CF.

## What did you do?

We treated 302 people (participants) with CF and PA lung infection in this study: 152 participants inhaled ALIS (once a day) and 150 participants inhaled TIS (twice a day) for 28 days followed by no treatment for 28 days. They repeated this treatment cycle three times. Participants were 6 years old or older, and about half of them were older than 18 years. We looked at how well participants could breathe when using either ALIS or TIS by measuring how much air they could breathe out (exhale) in one second. Participants also reported any health problems they had.

## What did you find?

At the end of each treatment cycle, participants who took ALIS could exhale as much as participants who took TIS. Participants from both groups had less PA in their sputum (phlegm), which showed that both treatments were killing the bacteria. Most participants had health problems during the study that could have been caused by the medication or by other health conditions. Some of these health problems were considered serious, and these were mostly pulmonary exacerbations of CF (sudden and temporary worsening of symptoms) that led to hospitalisation. Participants in both groups said their CF respiratory symptoms improved with treatment.

## What does this mean and reasons for caution?

Although amikacin is often given into the veins (intravenously), ALIS—which was made to be inhaled deep into the lungs—worked as well as TIS for PA lung infection and may be a possible treatment option for people with CF. Because this study was a short-term evaluation of treatments that would likely need to be used for a long time, any possible long-term effects of either treatment could not be looked at in this study.

## What's next?

In a second study lasting 2 years, we tested the safety of ALIS in people with CF and chronic (long-term) PA infection (28 days on treatment/28 days off) who took part in the first study. We have presented results at a scientific meeting and the full publication is in preparation.

## Original manuscript citation in PubMed

<https://www.ncbi.nlm.nih.gov/pubmed/?term=CLEAR-108+Study+Group>