Cystic Fibrosis Research News

Title:

Long-Term Amikacin Liposome Inhalation Suspension in Cystic Fibrosis Patients With Chronic *P. aeruginosa* Infection

Lay Title:

Using an Antibiotic Treatment Called Amikacin Liposome Inhalation Suspension (or ALIS) for Chronic Infection With *Pseudomonas aeruginosa* in People With Cystic Fibrosis for 2 years

Authors:

Diana Bilton[a], Isabelle Fajac[b,c], Tacjana Pressler[d], John Paul Clancy[e], Dorota Sands[f], Predrag Minic[g], Marco Cipolli[h], Ivanka Galeva[i], Amparo Solé[j], Alexandra L. Quittner[k], Zhanna Jumadilova[l], Monika Ciesielska[l], Michael W. Konstan[m], for the CLEAR-110 Study Group

Affiliations:

[a]Royal Brompton Hospital, Sydney Street, London SW3 6NP, United Kingdom;
[b]AP-HP, Centre-Université de Paris, 27, Rue du Faubourg Saint-Jacques, 75014, Paris, France;
[c]European Reference Network ERN-LUNG, Cystic Fibrosis Core Network;
[d]Cystic Fibrosis Center, Rigshospitalet (Hospital), Blegdamsvej 9, Copenhagen, Denmark-2100;
[e]Cincinnati Children's Hospital Medical Center, 3333 Burnet Ave, Cincinnati, Ohio 45229, USA; [f]Cystic Fibrosis Department, Institute of Mother and Child, 17a Kasprzaka Str. 01-211, Warsaw, Poland;
[g]Institute for Mother and Child Health Care, Department of Pulmonology, Medical School University of Belgrade, 6-8, Radoja Dakica Str. 11070, New Belgrade, Serbia;
[h]Cystic Fibrosis Center, Azienda Ospedaliera Universitaria Integrata, Piazzale Stefani, 1, 37126, Verona, Italy;
[i]Pediatric Clinic, Infants Department, Alexandrovska University Hospital, 1 Georgi Sofiiski Blvd 1431, Sofia, Bulgaria;
[j]Lung Transplant and Cystic Fibrosis Unit, Hospital Universitari i Politecnic La Fe, 46026, Valencia, Spain;
[k]Nicklaus Children's Research Institute, 3100 SW 62nd Ave, Miami, Florida 33155, USA;
[l]Insmed Incorporated, 700 US Highway 202/206, Bridgewater, New Jersey 08807, USA;
[m]Case Western Reserve University and Rainbow Babies and Children's Hospital, 10900 Euclid Avenue, Cleveland, Ohio 44106, USA

What was your research question?

Do people with cystic fibrosis (CF) who have lung infections caused by *Pseudomonas aeruginosa* (PA) bacteria have different health problems if they take an inhaled (breathed in) antibiotic called ALIS (amikacin liposome inhalation suspension) for additional treatment cycles for the total up to 2 years after taking ALIS for 6 months?

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Why is this important?

Many people with CF have lung infections that don't get better even after they take antibiotics, including antibiotics that they inhale (breathe into their lungs). Lung infections caused by PA are hard to cure because many antibiotics cannot destroy PA bacteria. If antibiotics are used for a long period of time the bacteria can become resistant to antibiotics. Sometimes people do not respond to certain antibiotics or experience side effects and are unable to tolerate long periods of treatment. Studies help doctors understand how well different antibiotics work in people with CF and how safe they are.

What did you do?

This 2-year study followed a 6-month study in which we compared ALIS to another antibiotic during 3 cycles of treatment (where each cycle was 28 days of treatment followed by 28 days of no treatment, or 56 days). In this study, we treated 206 people with ALIS for up to 12 cycles as before for up to a total of two years. One group of people was treated with ALIS in the first study and again in this study giving a total of 15 cycles, 2.5 years in total. Each month we checked how much PA bacteria was in people's lungs and if there were any health problems.

What did you find?

Within a treatment cycle, the amount of PA bacteria in people's lungs went down when on treatment and went up when off treatment. Also, people still had lung infections at the end of the study. Most people had health problems during the study that might or might not have been caused by ALIS. Some of these were serious and were mostly pulmonary exacerbations of CF (sudden and temporary worsening of symptoms) that led to hospitalization. The health problems reported in this 2-year study were similar to those in the previous shorter study.

What does this mean and reasons for caution?

ALIS is inhaled deep into the lungs and for each month it was taken PA bacteria levels in the lungs dropped. Lung infections caused by PA bacteria can be chronic (persisting) and need long-term treatment. In this study, treatment for 2 years did not cause different health problems compared to treatment for 6 months. Because everyone in this study was given ALIS, we cannot compare the safety of ALIS to other treatments, and the antibacterial activity of ALIS was not compared to other treatments.

What's next?

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Additional investigations using ALIS focused on lung disease caused by another bacterium, *Mycobacterium avium* complex (MAC). One study used ALIS with other antibiotics in people with persistent MAC infection despite at least 6 months of treatment. An ongoing study uses ALIS plus other antibiotics in people newly diagnosed with MAC.

Original manuscript citation in PubMed
https://pubmed.ncbi.nlm.nih.gov/34144923/