

# Cystic Fibrosis Research News

**Title:**

Evaluating the alginate oligosaccharide (OligoG) as a therapy for Burkholderia cepacia complex cystic fibrosis lung infection.

**Lay Title:**

Results from a clinical trial of the natural therapeutic alginate OligoG against Burkholderia lung infection in people with cystic fibrosis.

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**What was your research question?**

To evaluate the safety and explore the efficacy potential of the novel seaweed alginate drug candidate OligoG, to help treat Burkholderia lung infections in people with cystic fibrosis.

**Why is this important?**

Burkholderia infections are difficult to treat due to resistance of the bacteria to existing antibiotics and can lead to a fatal pneumonia in people with CF. Strict infection control measures, including segregation of infected patients have become the standard although such measures may have negative psychosocial effects among infected patients. Although these measures have had benefit in reducing transmission, Burkholderia infections remain a significant and life-threatening issue for people with CF. Previous experimental studies combining the novel alginate molecule OligoG with existing antibiotics (such as aztreonam) have shown improved effects against a wide range of multidrug-resistant bacteria including Burkholderia.

**What did you do?**

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In the clinical trial we evaluated the safety and antimicrobial effects of OligoG compared to a placebo in people with CF infected with Burkholderia while taking the antibiotic aztreonam. Seventeen people were enrolled at 2 sites in Germany. First they received either OligoG as a powder for inhalation (1050mg in 10 capsules) or a matching placebo of lactose for 28 days. This was followed by a washout period and a second 28-day treatment, so that all participants received both OligoG and placebo upon completion of the trial. Lung function, quality-of-life, sputum rheology and microbiological parameters were measured.

## What did you find?

Repeated inhalation of OligoG was safe in adults with CF. Adverse events were similar during OligoG and placebo treatment, with most events of mild severity in all treatment periods. There was no statistically significant improvement in lung function parameters for OligoG, although a promising reduction in total counts of Burkholderia bacteria suggests that inhaled OligoG might have some effect in reducing microbial burden and that this trend might be independent of aztreonam resistance. Sputum viscosity improved becoming more liquid after treatment with OligoG, and there were minor improvements in quality-of-life measurements, although these were not statistically significant.

## What does this mean and reasons for caution?

Although there were interesting trends for OligoG treatment in reducing the microbial burden of Burkholderia infection, this was not statistically significant and clearly a larger study is needed. The study also had a high treatment burden of 10 capsule inhalations three times daily, which clearly needs to be reduced and further studies are required to establish a more appropriate balance between efficacy and treatment burden.

## What's next?

Poor clinical outcome for Burkholderia infected individuals remains a major problem for which new therapeutics are still urgently required. Further clinical studies to determine the potential of OligoG in treating Burkholderia infected individuals will require enrolment from a wider range of CF centres.

## Original manuscript citation in PubMed

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