



**Cochrane**  
**Library**

Cochrane Database of Systematic Reviews

## Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis (Review)

Johansen HK, Gøtzsche PC

Johansen HK, Gøtzsche PC.  
Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis.  
*Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD001399.  
DOI: [10.1002/14651858.CD001399.pub3](https://doi.org/10.1002/14651858.CD001399.pub3).

[www.cochranelibrary.com](http://www.cochranelibrary.com)

[Intervention Review]

# Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis

Helle Krogh Johansen<sup>1</sup>, Peter C Gøtzsche<sup>1</sup>

<sup>1</sup>The Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark

**Contact address:** Helle Krogh Johansen, The Nordic Cochrane Centre, Rigshospitalet, Blegdamsvej 9, 3343, Copenhagen, DK 2100, Denmark. [hkj@cochrane.dk](mailto:hkj@cochrane.dk).

**Editorial group:** Cochrane Cystic Fibrosis and Genetic Disorders Group.

**Publication status and date:** New search for studies and content updated (no change to conclusions), published in Issue 6, 2013.

**Citation:** Johansen HK, Gøtzsche PC. Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD001399. DOI: [10.1002/14651858.CD001399.pub3](https://doi.org/10.1002/14651858.CD001399.pub3).

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

## ABSTRACT

### Background

Chronic pulmonary infection in cystic fibrosis results in progressive lung damage. Once colonisation of the lungs with *Pseudomonas aeruginosa* occurs, it is almost impossible to eradicate. Vaccines, aimed at reducing infection with *Pseudomonas aeruginosa*, have been developed.

### Objectives

To assess the effectiveness of vaccination against *Pseudomonas aeruginosa* in cystic fibrosis.

### Search methods

We searched the Cochrane Cystic Fibrosis and Genetic Disorders Group Trials Register using the terms vaccines AND pseudomonas (last search 30 May 2013) and PubMed using the terms vaccin\* AND cystic fibrosis (last search 30 May 2013).

### Selection criteria

Randomised trials (published or unpublished) comparing *Pseudomonas aeruginosa* vaccines (oral, parenteral or intranasal) with control vaccines or no intervention in cystic fibrosis.

### Data collection and analysis

The authors independently selected trials, assessed them and extracted data.

### Main results

Six trials were identified. Two trials were excluded since they were not randomised and one old, small trial because it was not possible to assess whether it was randomised. The three included trials comprised 483, 476 and 37 patients, respectively. No data have been published from one of the large trials, but the company stated in a press release that the trial failed to confirm the results from an earlier study and that further clinical development was suspended. In the other large trial, relative risk for chronic infection was 0.91 (95% confidence interval 0.55 to 1.49), and in the small trial, the risk was also close to one. In the large trial, one patient was reported to have died in the observation period. In that trial, 227 adverse events (4 severe) were registered in the vaccine group and 91 (1 severe) in the control group. There was a marked rise in flagella antibody titres in the vaccine group and no change in the placebo group ( $P < 0.0001$ ).

### Authors' conclusions

Vaccines against *Pseudomonas aeruginosa* cannot be recommended.

---

## PLAIN LANGUAGE SUMMARY

### **Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis**

Cystic fibrosis is a hereditary disease where thick mucus is produced in the lungs. *Pseudomonas aeruginosa* and other bacteria cause long-lasting lung infections which result in permanent lung damage. Vaccines aimed at reducing infection with *Pseudomonas aeruginosa* have been developed, and it is important to know whether vaccination can prevent lung infection. We searched for randomised controlled trials and included three trials with 483, 476 and 37 patients respectively. No data are available from one of the large trials, which is unpublished. In the other large trial and in the small trial, the risk of getting a chronic infection was not decreased. In the large trial, one patient was reported to have died in the observation period. In that trial, 227 adverse events (four severe) were registered in the vaccine group and 91 (one severe) in the control group. We cannot recommend the use of vaccines against *Pseudomonas aeruginosa*.