

Cochrane Database of Systematic Reviews - - Cochrane Review

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

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## Study design (if review, criteria of inclusion for studies)

Randomised trials (published or unpublished) comparing *Pseudomonas aeruginosa* vaccines (oral, parenteral or intranasal) with control vaccines or no intervention in cystic fibrosis.

## List of included studies (3)

Döring 2007; Lang 2004b; Langford 1983

## Participants

Patients with CF, diagnosed on the basis of abnormal sweat test or genotype, or both, of all ages and degrees of disease severity, regardless of the *P. aeruginosa* colonisation status.

## Interventions

Vaccines for preventing infection with *Pseudomonas aeruginosa*

## Outcome measures

Primary outcomes 1. Time to chronic *P. aeruginosa* infection 2. Pulmonary function (FEV1, FVC) 3. Mortality

## 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. In this large trial of a vaccine developed against flagella antigens, antibody titres against the epitopes contained in the vaccine were higher in the vaccine group compared to the placebo group (P

## Authors' conclusions

Vaccines against *Pseudomonas aeruginosa* cannot be recommended.

<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001399.pub4/abstract>

## See also

Johansen HK, Gøtzsche PC. Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis. Cochrane Database of Systematic Reviews 2018, Issue 8 Art. No.: CD001399. doi: 10.1002/14651858.CD001399.pub4

## Keywords

Bacterial Infections; Immunization; Infection; pharmacological\_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; *Pseudomonas* Vaccines; Respiratory Tract Diseases; Respiratory Tract Infections;