

The evaluation of Intra-bronchial and Nebulised Bacteriophage Treatment in Children with *Pseudomonas aeruginosa* (CHIP-CF)

ACTRN12622000767707

Status	RECRUITING
Sponsor	Respiratory Department, The Children's Hospital at Westmead
Enrollment	10 participants

Plain Language Summary

Cystic fibrosis (CF) is a genetic condition that causes thick mucus to build up in the lungs, making it very easy for bacteria to take hold. One particularly troublesome bacterium is *Pseudomonas aeruginosa*, which can be very difficult to clear with antibiotics alone. Bacteriophages — viruses that specifically target and destroy bacteria without harming human cells — are being explored as a new treatment option.

This study (CHIP-CF) tests whether bacteriophage therapy is safe and well-tolerated in children aged 6–18 with CF or other suppurative lung diseases who have chronic *Pseudomonas aeruginosa* infections that haven't fully responded to standard antibiotics. The bacteriophages are delivered both directly into the airways through a bronchoscope and then via a nebuliser (inhaler) twice a day for 7 days. Researchers will also check whether the treatment actually reduces *Pseudomonas* levels in sputum.

To be eligible, the child must have a confirmed CF or bronchiectasis diagnosis, have *Pseudomonas* in more than half of sputum cultures over the past year despite treatment, be able to perform breathing tests, and have bacterial samples that are sensitive to the available bacteriophages. The study is run by The Children's Hospital at Westmead.

Key Eligibility Criteria

Inclusion (6)

- Children and adolescents (from 6 years of age)
- A diagnosis of cystic fibrosis or presence of bronchiectasis or other conditions associated with suppurative lung disease.
- Positive sputum or bronchoalveolar lavage culture (*Pseudomonas aeruginosa*) in more than 50% of sputum samples over the past 1 year.
- Continues to isolate *Pseudomonas aeruginosa* in sputum despite undergoing *Pseudomonas aeruginosa* eradication therapy using two anti-pseudomonal antibiotics and/or is currently on suppressive treatment
- The latest clinical isolates of *Pseudomonas aeruginosa* taken within 3 months of enrolment are susceptible (demonstrates lytic activity) to available anti-*Pseudomonas aeruginosa* bacteriophages.

... and 1 more (see full listing online)

Exclusion (10)

- Children who have received more than 1mg/kg of Prednisolone continuously for more than 7 days before study enrolment.
- Children that require at least 18 hours/day of non-invasive ventilatory (NIV) support during admission.
- A current diagnosis of Allergic bronchopulmonary aspergillosis (ABPA).
- History of hemoptysis in the past 12 months prior to study enrolment.
- Prior known inability to expectorate sputum.

... and 5 more (see full listing online)

Locations (2 total)

The Children's Hospital at Westmead - Westmead, NSW, Australia
Sydney Children's Hospital, Randwick, NSW, Australia
<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000767707>

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