

Cystic Fibrosis Research News

Title:

ERADICATION OF EARLY P. AERUGINOSA INFECTION IN CHILDREN <7 YEARS OF AGE WITH CYSTIC FIBROSIS: THE EARLY STUDY

Authors:

Felix Ratjen^a, Alexander Moeller^b, Martha L. McKinney^c, Irina Asherova^d, Nipa Alon^e, Robert Maykut^f, Gerhild Angyalosi^g, EARLY study group[†]

[†]EARLY study group

Olga Bede (Szegedi Tudományegyetem AOK, Gyermekgyógyászati Központ, Szeged Hungary, Hungary)

Katalin Bolbas (Somogy Megyei Kaposi Mór Oktató Kórház, Kaposvár, Hungary)

Vladimir Bulatov (Kazan State Medical University, Kazan, Russia)

Elena Chertok (Voronezh Burdenko Medical Academy, Voronezh, Russia) Carla Colombo (Fond. IRCCS Ca' Granda, Osp. Maggiore Policlinico Univ. Studi, Milano MI, Italy)

Michael Fayon (Hôpital des enfants groupe Pellegrin, Bordeaux, France) Ferenc Gonczi (Kenezy Gyula Kórház és Rendelőintézet, Debrecen, Hungary) Essam Gouda (Clinical Research Center - Alexandria, Egypt)

Jutta Hammermann (Universitätsklinikum Carl Gustav, Carus, Dresden, Germany)

Anne Munck (Hopital Robert Debré, Paris, France)

Melinda Solomon (Hospital for Sick Children, Toronto, Ontario, Canada)

John Tsanakas (General Hospital of Thessaloniki, Hippokratiko, Thessaloniki GR, Greece)

Affiliations:

^aDivision of Respiratory Medicine, Department of Pediatrics, Physiology and Experimental Medicine, Hospital for Sick Children, University of Toronto, Toronto, ON, Canada

^bDivision of Respiratory Medicine, University Children's Hospital Zurich, Zurich, Switzerland

^cCHU Ste-Justine, Université de Montréal, Montréal, QC, Canada

^dYaroslavl's Children's Clinical Hospital, Yaroslavl, Russia

^eNovartis Pharmaceuticals Corporation, East Hanover, NJ, United States

^fRJMM Consulting, Montreal, QC, Canada

^gNovartis Pharma AG, Basel, Switzerland

Cystic Fibrosis Research News

What was your research question?

How effective is inhaled tobramycin solution (TOBI) in treating lung infections due to *Pseudomonas aeruginosa* in young children, between the ages of 3 months and 7 years.

Why is this important?

Pseudomonas aeruginosa is a bacterium, which is known to cause significant lung damage in individuals with cystic fibrosis. Various antibiotic treatment regimens are used in an attempt to eradicate infection early on and avoid chronic colonisation. While inhaled antibiotics are used, it is unclear as to how effective they are in treating early infections in children at this young age.

What did you do?

In a clinical study we have enrolled children between the ages of 3 months and up to 7 years of age with a positive culture for *Pseudomonas aeruginosa*. Patients received either TOBI or placebo for the first 28-days. Following the 28 days, patients who still cultured *Pseudomonas aeruginosa* received TOBI. Patients who did not have a positive culture for *Pseudomonas aeruginosa* at Day 28 could choose whether they wanted to receive study medication for an additional 28-Days or not. Patients who cleared the infection were followed for 12 months after the study to track their cultures. If another positive culture was reported, the patients received an additional 28-days of TOBI.

What did you find?

Patients with an early *Pseudomonas aeruginosa* infection that is treated shortly after the bacterium is detected, had more positive outcomes using TOB, than the patients whose treatment was postponed for a few weeks.

What does this mean and reasons for caution?

Our study has shown that early treatment of patients with *Pseudomonas aeruginosa* infection with TOBI can be effective in clearing the infection. The study has further found that earlier treatment might be better than delaying inhaled antibiotic therapy. However, the study was completed within a small number of patients (n=51) and the study design was complicated. Currently, TOBI is not approved for use in children less than 6 years of age.



Cystic Fibrosis Research News

What's next?

We hope that this new information will be useful for physicians as they decide how to treat early *Pseudomonas aeruginosa* infections, leading to more success in treating young children with cystic fibrosis.

Original manuscript citation in PubMed

<https://www.sciencedirect.com/science/article/pii/S1569199318300870>

Cystic Fibrosis Research News

cfresearchnews@gmail.com