

Reducing antibiotic duration does more harm than good for ear infections in young children

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Senior author and chief, Division of General Academic Pediatrics at Children's, and the Jack L. Paradise Endowed Professor of Pediatric Research at Pitt's School of Medicine. Credit: UPMC/Pitt Health Sciences

In a landmark trial conducted at Children's Hospital of Pittsburgh of UPMC and the University of Pittsburgh School of Medicine, researchers have demonstrated that when treating children between 9 and 23 months of age with antibiotics for ear infections, a shortened course has worse clinical outcomes without reducing the risk of antibiotic resistance or adverse events.

The results of the trial are published today in the *New England Journal of Medicine* and highlighted by an accompanying commentary.

Acute otitis media is a bacterial infection of the middle ear behind the ear drum which causes it to become painfully inflamed. Three out of four [children](#) experience this infection within their first year. Consequently, it is the most common reason why children are prescribed an antibiotic.

"Given significant concerns regarding overuse of antibiotics and increased [antibiotic resistance](#), we

conducted this trial to see if reducing the duration of antibiotic treatment would be equally effective along with decreased antibiotic resistance and fewer adverse reactions," said Alejandro Hoberman, M.D., chief, Division of General Academic Pediatrics at Children's, and the Jack L. Paradise Endowed Professor of Pediatric Research at Pitt's School of Medicine.

In the current trial, 520 children with [acute otitis media](#) were randomly assigned to either a standard 10-day regimen of the antibiotic amoxicillin-clavulanate or a shortened 5-day treatment followed by five days of placebo. Neither the study participants nor the physicians knew which group the participant was assigned to.

Children were followed starting in October through the rest of the annual respiratory-infection season, and had a final visit during the following September.

They found that the risk of treatment failure in the 5-day group (34 percent) was more than twice as much the risk in the 10-day group (16 percent). The results were significant when considering the trial design which was set up to find out whether the 5-day treatment would be as good as the 10-day regimen, Dr. Hoberman said. Instead, the results clearly showed that not only was their initial assumption proven wrong, but the 10-day treatment was far more effective.

When they tested the presence of antibiotic-resistant bacteria through nasopharyngeal (back of the nose) swabs, there was no decrease in the 5-day group as might have been expected with a shorter duration of antibiotics. Also, reduced-duration antibiotics did not decrease the risk of frequent [adverse events](#) like diarrhea or diaper rash.

When testing the risk of a recurrent infection, they found that it was higher when children were exposed to three or more children for 10 or more hours per week, such as in a day care setting, or if the initial infection occurred in both ears as opposed to just one ear.

Importantly, the study also showed for the first time that almost one in two children in whom residual fluid was observed in the middle ear after treatment had a recurring infection, a significantly higher percentage when compared to children without any residual fluid in the [middle ear](#).

The marked superiority of the 10-day regimen over the 5-day regimen led the independent safety monitoring board overseeing the trial to conclude it prematurely as the primary end point was achieved.

"The results of this study clearly show that for treating [ear infections](#) in children between 9 and 23 months of age, a 5-day course of antibiotic offers no benefit in terms of adverse events or antibiotic resistance. Though we should be rightly concerned about the emergence of resistance overall for this condition, the benefits of the 10-day regimen greatly outweigh the risks," said Dr. Hoberman.

More information: Alejandro Hoberman et al, Shortened Antimicrobial Treatment for Acute Otitis Media in Young Children, *New England Journal of Medicine* (2016). DOI: 10.1056/NEJMoa1606043

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