

Research Study:

Treatment of Acute Otitis Media (AOM), 10 versus 5 Days of Antibiotics*

A study sponsored by the National Institutes of Health that is relevant to you and your child

- Your child has an ear infection. Children's Hospital of Pittsburgh of UPMC has a research program for children with ear infections.
- We know that treatment with antibiotics helps resolve symptoms of an ear infection sooner.
- We also know that antibiotics can have side effects of which the most frequent are diarrhea and diaper rash.
- We also know that overuse of antibiotics can make bacteria become resistant, and then the antibiotic does not work.
- What we do *not* know is whether 5 days of antibiotics, rather than 10 days, may be all that your child needs. A shorter course may lead to less resistant germs and fewer side effects while still treating the ear infection properly.

What happens in this study?

- We will enroll 600 children, ages 6 through 23 months with an ear infection.
- Your child will be given the antibiotic Augmentin, which has been shown to be the most effective, for either 5 or 10 days. This is not a new drug; Augmentin has been approved by the Food and Drug Administration (FDA). We will give you the medicine today, so you will not have to go to the pharmacy.
- We will give you two bottles. The bottle for the first 5 days will be antibiotic for all children. The second bottle for days 6-10 will be antibiotic for half of the children or placebo for the other half of the children. Placebo tastes and looks like the antibiotic but has no medicine in it. Neither you nor we will know which treatment your child is receiving during Days 6-10. Only the researchers will know which children are in which group.
- We will call you in 4-6 days to see how your child is improving, and will see him/her back in 2 weeks to check that the ear infection is cured. If it is not better we will treat him/her until the ear infection resolves.

* Full study title: Efficacy of Short-Course Antimicrobial Treatment for Young Children With Acute Otitis Media and Impact on Antimicrobial Resistance, ClinicalTrials.gov Identifier: NCT0151107

- Your child will be seen by our team of doctors and nurse practitioners, who are experts at looking at young children's ears, every 6 weeks until the end of May.
- There will be a final study visit after the summer, in September. All visits will be in this office.
- We are available 24/7 to answer any questions you may have, and will see your child when you have any concerns that he/she may have another ear infection. If that happens, we will give him/her the same duration of antibiotic treatment (5 or 10 days) that we will be giving today.
- At most visits, we will look at the ears, get a picture of the ear drum and obtain a nose culture to look for resistant germs.
- There is free parking and all participants will be paid \$20 for each study visit to help cover travel expenses. At the last visit, you will be paid \$40 if you have attended most of the scheduled study visits.
- Dr. Hoberman can be reached on the program's cell phone, 412-999-EARS (3277), if you have any questions or concerns at any time.

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