

Ear Infection Study

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

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Background: AOM is the most frequently occurring infection in children for which antimicrobial agents are prescribed in the US. This study is likely to result in a definitive recommendation involving limiting the duration of antimicrobial therapy for AOM. Such a strategy would result in up to a 50% reduction in overall antibiotic utilization for this condition.

Methods: Eligible subjects will be randomized to one of two study treatment groups:

1. Standard duration: Amoxicillin-clavulanate potassium in 2 divided doses for 10 days
2. Reduced-duration: Amoxicillin-clavulanate potassium in 2 divided doses for 5 days (Days 1-5) followed by placebo in 2 divided doses for 5 days (Days 6-10).

Inclusion

- 6 to 23 months
- Clinical diagnosis of AOM
- Fever or symptoms (ear pain, rubbing/ pulling/ holding ears, irritability) within the past 48 hours

Exclusion

- Serious health or medical conditions
- Allergy to penicillin
- Currently taking antibiotics

Benefits to participants: Children in the study will receive antibiotics and close monitoring. Parents will have 24 hour access to Dr. Hoberman. Compensation provided

Benefits to referring doctors: The results of this study will assist health care providers in making decisions regarding the use of antibiotics for treating children with ear infections and may slow the spread of resistant germs.



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