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# Baltimore

#### ORIGINAL ARTICLE

### A Placebo-Controlled Trial of Antimicrobial Treatment for Acute Otitis Media

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The efficacy of antimicrobial treatment in children with acute otitis media remains controversial.

# **Methods**

- Randomized, double-blind trial, children 6 to 35 months of age with AOM, strict criteria diagnosed, received amoxicillin—clavulanate 40/5.7 MKD (161 children) or placebo (158 children) for 7 days.
- F/U d3, d8
- The primary outcome was the time to treatment failure from the first dose until the end-oftreatment visit on day 8.

## **Methods**

 The definition of treatment failure was based on the overall condition of the child (including adverse events) and otoscopic signs of AOM.