



## ORIGINAL ARTICLE

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Volume 316:432-437

February 19, 1987

Number 8

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## Efficacy of amoxicillin with and without decongestant-antihistamine for otitis media with effusion in children. Results of a double-blind, randomized trial

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### Abstract

In a randomized, double-blind, placebo-controlled trial involving 518 infants and children who had otitis media with effusion ("secretory" otitis media), we evaluated the efficacy of a two-week course of amoxicillin (40 mg per kilogram of body weight per day) with and without a four-week course of an oral decongestant-antihistamine combination. Among the 474 subjects who were evaluated at the four-week end point, the rate of resolution of middle-ear effusion was twice as high in those treated with amoxicillin, either with or without the decongestant-antihistamine, as in those who received placebo ( $P$  less than 0.001), but 69.8 percent of the amoxicillin-treated subjects still had effusion. Among both the amoxicillin-treated subjects and the placebo-treated subjects, resolution was more likely in those with initially unilateral effusion, in those who had had effusion for eight weeks or less, and in those without an upper respiratory tract infection at the four-week end point. Side effects were reported more often in subjects who received decongestant-antihistamine than in those who did not. Among the subjects without effusion at the four-week end point, recurrent effusion developed in approximately half those in both the amoxicillin and placebo groups during the subsequent three months. We conclude that in infants and children with otitis media with effusion, amoxicillin treatment increases to some extent the likelihood of resolution.

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