

Abstract

Background: Current guidance suggests oral antibiotics can be considered for children with acute otitis media (AOM) and ear discharge, but there is an absence of evidence regarding the relative effectiveness of antibiotic-corticosteroid eardrops.

Aim: To establish whether antibiotic-corticosteroid eardrops are non-inferior to oral antibiotics in children with AOM and ear discharge.

Design and setting: Open randomised controlled non-inferiority trial set in Dutch primary care.

Methods: Children were randomised to hydrocortisone-bacitracin-colistin eardrops or amoxicillin oral suspension for 7 days. Primary outcome was proportion of children with resolution of ear pain and fever at day 3.

Results: Between December 2017 and March 2023, 58 of a planned 350 children were recruited due to slow accrual for various reasons. Children assigned to eardrops (n=26) had lower resolution rates of ear pain and fever at 3 days compared to those receiving oral antibiotics (n=31): 42% vs 65%; adjusted risk difference 20.3%, 95% confidence interval -5.3% to 41.9%), longer parent-reported ear discharge (6 vs 3 days; $p=0.04$), and slightly higher mean ear pain scores (Likert scale 0-6) over days 1-3 (2.1 vs 1.4, $p=0.02$), but received fewer oral antibiotic courses in three months (11 for 25 children vs 33 for 30 children), and had less GI upset and rash (12% vs 32% and 8% vs 16%, respectively).

Conclusion: Early termination stopped us from determining non-inferiority of antibiotic-corticosteroid eardrops. Our limited data, requiring confirmation, suggest that oral antibiotics may be more effective than antibiotic-corticosteroid eardrops in resolving symptoms and shortening the duration of ear discharge.