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Comparative Effectiveness and Adverse Effects of Azithromycin and Amoxicillin/Clavulanate in Pediatric Acute Otitis Media: A Meta-Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 November 2024 and was last updated on 7 November 2024.

INTRODUCTION

Review question / Objective This study aims to conduct a meta-analysis of randomized controlled trials comparing the efficacy and adverse effects of azithromycin versus amoxicillin/clavulanate in treating pediatric acute otitis media. The goal is to offer comprehensive insights into their relative effectiveness and safety, aiding clinical treatment decisions for children.

Condition being studied The focus is on pediatric acute otitis media (AOM), evaluating the effectiveness and safety of azithromycin and amoxicillin/clavulanate.

METHODS

Participant or population Children diagnosed with acute otitis media, presenting with common symptoms such as ear pain, fever, and tympanic membrane erythema.

Intervention Azithromycin treatment for children with acute otitis media.

Comparator Amoxicillin/clavulanate treatment for children with acute otitis media.

Study designs to be included RCTs.

Eligibility criteria Eligible studies include randomized controlled trials (RCTs) involving children with acute otitis media, comparing azithromycin and amoxicillin/clavulanate, and reporting relevant outcomes like cure, failure, recurrence, and adverse events.

Information sources Systematic searches were conducted across PubMed, Embase, Cochrane Library, Web of Science, ClinicalTrials.gov, CNKI, WanFang Data, VIP, and CBM, supplemented by manual searches for additional studies.

Main outcome(s) Cure rates, failure rates, recurrence, adverse event incidence, and laboratory abnormalities related to treatment.

Quality assessment / Risk of bias analysis The Cochrane Risk of Bias (RoB) tool was used to evaluate study domains, such as randomization, allocation concealment, blinding, and data integrity. Each was categorized as "low," "unclear," or "high" risk.

Strategy of data synthesis Meta-analyses were conducted using RevMan 5.4 and Stata 17.0, with risk ratios (RRs) and 95% confidence intervals (CIs) calculated for dichotomous outcomes. Heterogeneity was assessed using Cochran's Q and I^2 statistics. Depending on the degree of heterogeneity, fixed or random-effects models were applied. Subgroup and sensitivity analyses were performed, and publication bias was assessed using Egger's and Begg's tests. Evidence quality was graded using the GRADE system, and Trial Sequential Analysis (TSA) verified the adequacy of the sample size.

Subgroup analysis This analysis explored the impact of factors such as patient age and study variations on treatment outcomes to determine if characteristics influenced relative efficacy or safety.

Sensitivity analysis Sensitivity tests assessed the stability of findings by reanalyzing data after excluding individual studies to ensure consistent and reliable results.

Country(ies) involved China.

Keywords Acute otitis media; Pediatrics; Azithromycin; Amoxicillin/clavulanate; Meta-analysis.

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