Effectiveness of analgesic ear drops as add-on treatment to oral analgesics in children with acute otitis media: the OPTIMA pragmatic randomised controlled

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ABSTRACT

Background: Clinical practice guidelines recommend clinicians to use oral analgesics in all children with acute otitis media (AOM) to relieve symptoms. While analgesic ear drops could be a promising add-on treatment, evidence for their effectiveness is limited.

Aim: To assess whether analgesic ear drops added to usual care provide superior ear pain relief over usual care alone in children presenting to general practice with AOM.

Design and setting: Pragmatic, two arm, individually randomised, open, superiority trial in 35 general practices in the Netherlands between October 2021 and January 2024.

Methods: Children were randomly allocated to either 1) lidocaine hydrochloride 5mg/g ear drops 1-2 drops up to six times daily for a maximum of 7 days in addition to usual care (oral analgesics with/without antibiotics) or 2) usual care. The primary outcome, parent-reported ear pain score (0-10) over the first 3 days, was analysed with a linear regression model with a GEE-type matrix for repeated measurements, adjusting for baseline ear pain score, age (≤2 vs >2 years), AOM laterality (uni- vs bilateral), and baseline antibiotic prescribing (yes vs no). Secondary outcomes were reported descriptively.

Results: With 29 of a planned 300 children enrolled (15 intervention, 14 control; mean age 2.6 years (SD 1.5), 62% boys), the trial was ended prematurely due to slow accrual. Follow-up data were unavailable for one participant in the intervention group; therefore, analyses were conducted with the remaining 28 participants. After adjustment, we found no evidence of a difference in mean parent-reported ear pain scores over the first 3 days between children receiving analgesic ear drops plus usual versus usual care alone (mean difference: 0.14, 95% CI -2.00 to 2.28). The proportions of children consuming antibiotics in the first 7 days were 57.1% (8/14) and 42.9% (6/14), respectively. Local discomfort and difficulties during administration of the analgesic ear drops were reported in 71.4% (10/14) and 50% (7/14) of children, respectively.

Conclusions: Early termination stopped us from determining the superiority of analgesic eardrops plus usual care over usual care alone in children with AOM. Combining individual participant trial data may provide more robust conclusions by deriving a larger sample size.

Trial registration: The Netherlands Trial Register; NL9500. Date of registration: 28 May 2021.