Articles

Oral prednisolone in preschool children with virus-associated wheeze: a prospective, randomised, double-blind, placebo-controlled trial

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Article Info

Summary

Background

Children of preschool age often have episodes of virus-associated wheeze, and research assessing efficacy of corticosteroids for paediatric wheeze exacerbations is inconclusive.

Methods

This non-inferiority, randomised, double-blind, placebo-controlled trial was to compare the efficacy of placebo versus oral prednisolone in children aged 24–72 months presenting with virus-associated wheeze at the paediatric emergency department of Princess Margaret Hospital in Perth, WA, Australia. Eligible participants were randomly assigned (1:1) using a computer-generated random number program to receive placebo or prednisolone (1 mg/kg per day) for 3 days. The primary outcome was total length of stay in hospital until ready for discharge. Following an analysis to test the hypothesis that placebo is non-inferior to prednisolone, a post-hoc superiority analysis was done to test the hypothesis that prednisolone was superior to placebo. A non-inferiority margin of 10% was used to establish non-inferiority. Efficacy analyses were on a modified intention-to-treat basis, whereby patients were excluded from the final efficacy analysis if consent was withdrawn, two doses of study drug were vomited, or paperwork was lost. All participants were included in safety analyses. This study is registered with the Australian and New Zealand Clinical Trials Registry, number ACTRN12612000394842.

Findings

Between June 11, 2012, and June 10, 2015, we screened 3727 patients for eligibility. 624 eligible patients were randomly assigned to treatment, and 605 patients were included in the modified intention-to-treat analysis (300 patients from the placebo group, 305 patients from the prednisolone group). The median length of stay until ready for discharge was longer in the placebo group (540 min [IQR 124–971]) than in the prednisolone group (370 min [121–709]); placebo was inferior to prednisolone. In the post-hoc superiority analysis of 605 patients, the unadjusted ratio of geometric mean for length of stay was 0·79 (95% CI 0·64–0·97; p=0·0227) for the prednisolone group relative to the placebo group. No serious adverse events were reported during the study or follow-up period. One child in the placebo group had a non-specific maculopapular rash, which resolved spontaneously. Two children (one from each group) were reported to be hyperactive during follow-up assessments.

Interpretation

Oral prednisolone had a clear benefit over placebo at reducing the length of stay in children presenting to a paediatric emergency department with virus-associated wheeze and was well tolerated.

Funding

Western Australian Department of Health.

COMMENT
Oral corticosteroids reduce length of hospital stay for preschool children with virus-associated wheeze

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