

Background Attacks of wheezing induced by upper respiratory viral infections are common in preschool children between the ages of 10 months and 6 years. A short course of oral prednisolone is widely used to treat preschool children with wheezing who present to a hospital, but there is conflicting evidence regarding its efficacy in this age group.

Methods We conducted a randomized, double-blind, placebo-controlled trial comparing a 5-day course of oral prednisolone (10 mg once a day for children 10 to 24 months of age and 20 mg once a day for older children) with placebo in 700 children between the ages of 10 months and 60 months. The children presented to three hospitals in England with an attack of wheezing associated with a viral infection; 687 children were included in the intention-to-treat analysis (343 in the prednisolone group and 344 in the placebo group). The primary outcome was the duration of hospitalization. Secondary outcomes were the score on the Preschool Respiratory Assessment Measure, albuterol use, and a 7-day symptom score.

Results There was no significant difference in the duration of hospitalization between the placebo group and the prednisolone group (13.9 hours vs. 11.0 hours; ratio of geometric means, 0.90; 95% confidence interval, 0.77 to 1.05) or in the interval between hospital admission and signoff for discharge by a physician. In addition, there was no significant difference between the two study groups for any of the secondary outcomes or for the number of adverse events.

Conclusions In preschool children presenting to a hospital with mild-to-moderate wheezing associated with a viral infection, oral prednisolone was not superior to placebo. (Current Controlled Trials number, ISRCTN58363576 [controlled-trials.com] .)

Trial design template:

Eligibility criteria	<ul style="list-style-type: none">• children between the ages of 10 months and 60 months;• the children presented to three hospitals in England with an attack of wheezing associated with a viral infection
Sample size	700
Start date of enrolment	
End date of enrolment	
Name of experimental treatment	prednisolone
Name of control treatment	placebo
Dose	<ul style="list-style-type: none">• 10 mg for children 10 to 24 months of age• 20 mg for older children
Frequency of treatment	once a day
Route of treatment	oral
Duration of treatment	5-day
Primary outcome name	the duration of hospitalization
Primary outcome time point	
Secondary outcome name	<ul style="list-style-type: none">• the score on the Preschool Respiratory Assessment Measure;• albuterol use;• a 7-day symptom score
Secondary outcome time point	7-day
Funding organization name	
Funding number	
Early stopping	
Registration identifier of trial	ISRCTN58363576
Author name	Panickar J
Date of publication	2009 Jan 22
DOI	