



Medicine by the Numbers

A Collaboration of *TheNNT.com* and AFP

The NNT Group rating system:

Green: Benefits greater than harms

Yellow: Unclear benefits

Red: No benefits

Black: Harms greater than benefits

► Ondansetron for Gastroenteritis in Children and Adolescents

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ONDANSETRON (ZOFRAN) FOR GASTROENTERITIS IN CHILDREN AND ADOLESCENTS

NNT = 5 for cessation of vomiting

Benefits	Harms
Vomiting stopped (NNT = 5)	Diarrhea was a consistent adverse effect, but due to varying measurements, the NNH could not be calculated
Intravenous hydration avoided (NNT = 6)	
No admissions were avoided	

NNH = number needed to harm; NNT = number needed to treat.

Details for This Review

Study Population: Children younger than 18 years who presented to the emergency department with vomiting and a clinical diagnosis of gastroenteritis

Efficacy End Points: Cessation of emesis, hospitalization, intravenous rehydration, readmission to the emergency department within 72 hours

Harm End Points: Medication adverse effects (diarrhea)

Narrative: Three studies examined administration of weight-based oral ondansetron (Zofran) vs. a placebo, totaling 465 patients.¹ Included were children younger than 18 years who presented with vomiting and a clinical diagnosis of gastroenteritis. Excluded were children who were under the effects of general anesthesia; who were undergoing chemotherapy; or who had surgical conditions, metabolic disorders, or systemic infections.

The mainstay of gastroenteritis treatment in the emergency department involves rehydration, preferably through oral means. The studies demonstrated a reduction in intravenous rehydration rates (relative risk = 0.57; number needed to treat = 6; 95% confidence interval, 4 to 13) and an increase in cessation of vomiting (relative risk = 1.34; number needed to treat = 5; 95% confidence interval = 3 to 7).

Caveats: In general, the evidence quality for the involved trials was noted to be low to mid grade, and although the total number of patients was just more than 1,000, most outcome measure comparisons reported in these reviews included fewer than 500 patients total, making the confidence intervals wide and the findings somewhat less robust. Ondansetron appears to reduce vomiting among children with gastroenteritis. Whether the drug reduces hospital admission rates appears controversial. This Cochrane review showed an immediate admission benefit; however, a statistically similar proportion of children were admitted by 72 hours, suggesting that ondansetron delayed rather than avoided hospital admission.¹

A number of studies reported an increase in diarrhea in the ondansetron group. This could not be quantified because of varying use of end points and outcome measures, but increased diarrhea appeared to be a fairly consistent finding. In addition, the U.S. Food and Drug Administration has issued a warning for increased QT interval (and potential torsades de pointes arrhythmia) associated with ondansetron use, although the frequency and danger of this are unknown, and no study reported any cardiac effects, apparent arrhythmia events, or unexplained sudden deaths.²

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This review is available from the NNT Group at <http://www.thennt.com/nnt/ondansetron-for-pediatric-gastroenteritis/>.

Author disclosure: No relevant financial affiliations.

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- U.S. Food and Drug Administration. FDA drug safety communication: abnormal heart rhythms may be associated with use of Zofran (ondansetron). June 29, 2012. <http://www.fda.gov/Drugs/DrugSafety/ucm271913.htm>. Accessed January 14, 2015. ■