Appendix 2. Trial Outcomes and Reported Adverse Symptoms According to Randomization to Ondansetron or Metoclopramide (Cases With Significant Bacteriuria Excluded)

	Ondansetron n = 72	Metoclopramide n = 74	*P*	Relative Risk (95% CI)	NNTb* (95% CI)
Primary Outcomes					
Vomiting episodes	1 [0-2]	1 [0-3]	0.38		
Well-being VNRS†	9 [8-9]	9 [7-10]	0.64		
n = 144‡	8.6 ± 1.2	8.3 ± 1.6	0.27		
Secondary outcomes					
Vomit-free during 24-hour study period	34 (47.2)	31 (41.9)	0.62	1.2 (0.6-2.4)	
Nausea score§ at					
recruitment	8 [7-9]	9 [7-10]	0.18		
8 hours	4 [3-6]	5 [4-6]	0.05		

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16 hours	3 [1-4]	3 [2-5]	0.29		
n = 145‡					
24 hours	1 [1-3]	2 [1-3]	0.63		
n = 141‡					
Repeated measures analysis of variance for			0.13		
nausea score					
n = 141‡					
Hospital Stay (days)	1.9 [1.5-2.4]	2.0 [1.7-2.7]	0.10		
Ketonuria (dipstick) at 24 hours			0.02	0.4 (0.2-0.9)	7 (3.5-32.5)
Nil	63 (87.5)	53 (71.6)	0.05		
1+	5 (6.9)	12 (16.2)			
2+	4 (5.6)	5 (6.8			
3+	0 (0.0)	4 (5.4)			

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Trial drug not completed (all events)	4/72 (5.6)‖	2/74 (2.7)‖	0.44	2.1 (0.4-12)	
Trial drug not completed (adverse events)	0/72 (0)	1/74 (1.4)	1.00		
Open label anti-emetic after trial drug	11 (15.3)	13 (17.6)	0.82	0.8 (0.4-2.0)	
Symptoms profile by questionnaire¶					
Felt drowsy	8/72 (11.1)	22/74 (29.7)	0.01	0.3 (0.1-0.7)	6 (3.2-16.9)
Unable to sleep	6/72 (8.3)	8/74 (10.8)	0.78	0.8 (0.2-2.3)	
Had dry mouth	6/72 (8.3)	17/74 (23.0)	0.02	0.3 (0.1-0.8)	7 (3.8-32.0)
Felt dizzy	5/72 (6.9)	13/74 (17.6)	0.08	0.4 (0.1-.1.0)	
Had diarrhoea	0/72 (0.0)	3/74 (4.1)	0.25		
Had headache	8/72 (11.1)	10/74 (13.5)	0.80	0.8 (0.3-2.2)	
Experienced Palpitations	2/72 (2.8)	4/74 (5.4)	0.68	0.5 (0.1-2.8)	
Involuntary muscle movement (dystonia)	0/72 (0.0)	0/74 (0.0)			
Noticed skin rash	1/72 (1.4)	1/74 (1.4)	1.00	1.0 (0.1-17)	

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NNTb, number needed to treat to benefit; CI, confidence interval; VNRS, visual numerical rating scale.

Data are median [interquartile range] for ordinal and nonnormally distributed data, mean ± standard deviation for continuous data, or number (%) for categorical data unless otherwise specified. Normality of data distribution was tested using the Kolmogorov Smirnov test. Analysis was by Mann Whitney U test for nonnormally distributed or ordinal data. Student t test was also used to analyze well-being VNRS score. The Fisher's exact test is used for categorical 2 x 2 data sets and Chi Square test for larger categorical data sets.

*Number needed to treat to benefit with ondansetron compared with metoclopramide (only stated where bivariate $P < 0.05$)

†Well-being 10-point VNRS with range from 1 to 10 (higher score greater well-being) self-scored by participants at 24 hours after randomization.

‡Missing or incomplete data resulting in $n < 146$, due to participants incompletely filling VNRS score sheets or side effects questionnaire.

§Nausea is self-scored by participants using a 10-point visual numerical rating scale (VNRS) with a score of 1 to 10 (higher score worst nausea) at enrollment, 8, 16, and study completion at 24 hours after randomization.

‖Four participants randomized to ondansetron did not receive the full course of four doses of allocated study drug (three participants requested to stop further anti-emetic medication when symptomatically better, one decided to withdraw from receiving study drug on her own accord but continued to cooperate with VNRS scoring and questionnaire. Two participants randomized to metoclopramide did not receive the full course — one requested to stop further antiemetic medication when symptomatically better and another had a significant skin rash presumed to be an allergic reaction and the study drug was stopped).

¶Symptoms questionnaire was self-answered at 24 hours after randomization regarding symptoms experienced since trial enrollment.

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