

Triage Administration of Ondansetron for Gastroenteritis in children; a randomized controlled trial

O Weill, MD¹; J Gravel, MD, MSc¹; B Bailey, MD, MSc¹; C Marquis BPharm MSc²; N Lucas, MD¹

Department of Pediatrics, CHU Sainte-Justine, Montréal, Canada; Department of Pharmacy, CHU Sainte-Justine, Université de Montréal, Montréal, Canada

INTRODUCTION

- Ondansetron is effective to decrease hospitalisation of children with gastro-enteritis
- Nurse-led initiative at triage can improve flow through the ED
 Administration at triage of and processor may be beneficial.
- Administration at triage of ondansetron may be beneficial

OBJECTIVES

 To assess the effectiveness of triage nurse-initiated administration of ondansetron for children with suspected gastroenteritis in the paediatric emergency department to reduce the number of patients requiring ED observation following first physician assessment.

METHODS

- Study design: A randomized double –blind clinical trial
 Setting:
- A tertiary care paediatric emergency department
- Montreal
- 2018-2020
- Participants (convenience sample):

Inclusion: Age 6 months to 17 years

Suspected gastro-enteritis (> 3 vomiting)

Exclusion:

Severe dehydration

Bloody stool/ hematemesis

Past abdominal surgery Allergy to ondansetron

Long Qt syndrome

Consent problem

Study financially supported by CHU Sainte-Justine Foundation No study member have any potential conflict of interest. This study did not demonstrate any benefit in using ondansetron at triage for children with presumed gastroenteritis.

Tx success: 44% ondansetron Vs. 45% placebo

Difference: 1% (95% CI -20% to 19%)

Intervention:

Ondansetron provided just after triage (2, 4 or 8 mg) Placebo (sucrose solution)

Primary outcome:

Intervention success defined by ED discharge immediately after 1st medical evaluation

Secondary outcomes:

ED length of stay Number of vomiting Disposal Return to the ED

Randomization and concealment: Block randomization of variable size 1:1 ratio

Block randomization of variable size 1:1 ratio
Concealment with opaque envelopes
Study medication prepared before by pharmacy

Procedure:

Participants identified by triage nurses
Consent obtained at triage by a research nurse
Intervention after signature of the consent
Standardized rehydration 15mL per 15 minutes
Evaluation by an ED physician
Phone follow-up at 72 hours

• Ethics:

Informed consent signed by patients/families

RESULTS

Characteristics	Ondansetron	Placebo n= 47	
	n=43		
Median age in months (IQR)	36 (26, 75)	53 (24, 72)	
Median weight in Kg (IQR)	15 (12, 21)	15 (13, 23)	
Sex male (%)	24 (56)	26 (55)	
Vomiting in previous 24h			
• 3-5	• 6 (14)	• 3 (6)	
• 6-10	• 20 (47)	• 19 (40)	
• >10	• 17 (40)	• 25 (53)	
Length of symptoms:			
• 0-4h	• 2 (7)	• 3 (10)	
• 4-<24h	• 6 (19)	• 6 (19)	
• 24-<72h	• 6 (19)	• 5 (16)	
• >= 72h	• 17 (55)	• 17 (55)	
Median wait time in minutes to s physician	see 163 (125, 213)	160 (126, 211)	

Outcomes	Ondansetron	Placebo	Difference in
	n=43	n=47	% (95% CI)
Patients discharged immediately after	19 (44)	21 (45)	-1 (-20 to 19)
initial medical assessment			
Oral rehydration volume (mL) at	60	58	2 (-18 to 21)
physician evaluation			
Any vomiting before seeing the	12 (28)	6 (13)	15 (-2 to 31)
physician			
Need for rescue medication	17 (40)	10 (21)	19 (-0.6 to 36)
Need for IV rehydration	6 (14)	3 (6)	8 (-6, 22)
Median length of stay after physician	72 (17, 194)	68 (20, 140)	p=0.821*
evaluation			
Median ED length of stay	232 (180, 395)	227 (180, 335)	p= 0.677*
Return to the ED in the following 48h	3 (7)	4 (9)	-2 (-14 to 11)