




# Effectivity of Esomeprazole Compared with Lansoprazole in the Treatment of Pediatric with Gastritis

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## Abstract

**Edited by:** Ksenija Bogoeva-Kostovska  
**Citation:** Kollins F, Supriatmo S, Saragih R, Ilhamd I. Effectivity of Esomeprazole Compared with Lansoprazole in the Treatment of Pediatric with Gastritis. Open Access Maced J Med Sci. 2021 Oct 23; 9(B):1424-1427. https://doi.org/10.3889/oamjms.2021.7191

**Keywords:** Effectivity; Children; Gastritis; Esomeprazole; Lansoprazole

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**Received:** 01-Sep-2021

**Revised:** 06-Oct-2021

**Accepted:** 13-Oct-2021

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**Funding:** This research did not receive any financial support

**Competing Interests:** The authors have declared that no competing interests exist

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**BACKGROUND:** The administration of proton pump inhibitor (PPI) therapy in pediatric patients has also increased dramatically during the last three decades. Clinical trials comparison of esomeprazole and lansoprazole for pediatric were limited.

**AIM:** This study focused on comparing the effectivity of Esomeprazole with lansoprazole for healing gastritis symptoms in pediatric patients.

**METHODS:** A randomized and single blind (assessors) controlled clinical trial was done at H. Adam Malik hospital at Medan. Patients that complied with study's criteria and signed informed consent were collected information about the symptoms. Confirmation diagnosis of gastritis by gastroscopy, then randomized into lansoprazole treatment group (15 mg if < 30 kg and 30 mg if > 30 kg) or esomeprazole treatment group (0,4–0,8 mg per Kg body weight). Medication for both groups will be given orally for 14 days, then evaluated for the initial symptoms. p-value of this study was calculated with the  $\chi^2$  test.

**RESULTS:** Fifty two patients confirmed gastritis were enrolled in this study; 27 patients received lansoprazole and 25 patients received esomeprazole. There was no difference of effectivity between the two groups for vomiting, hematemesis, and nausea. Lansoprazole treatment for 14 days has a significant difference for abdominal pain recovery from esomeprazole treatment. The lansoprazole groups have 92% free of abdominal pain compared to the esomeprazole group for only 66% free of abdominal pain.

**CONCLUSION:** There was no significant difference between lansoprazole and esomeprazole therapy.

## Introduction

Gastritis is a common medical problem that is frequently underestimated can be a troublesome disease for children. The overall incidence of gastritis in pediatric is still not determined. A Canadian study showed approximately 1 of 2500 pediatrics were admitted to hospital diagnosed with gastritis [1]. The imbalance of aggressive factors and mucosal defensive is the cause of gastric mucosa inflammation. Abdominal pain is a common symptom of gastritis due to mucosal ulceration. Knowledge of gastritis and mucosal ulceration are very important for the treatment of abdominal pain in pediatric [2].

Usage of proton pump inhibitor (PPI) for pediatrics has been increased dramatically. Studies showed that PPIs prescriptions from 1999 to 2000 for pediatric < 12 months have increased 7.5 folds [3]. PPIs have superiority effect by inhibit terminal pathway of gastric acid secretion and can be given once daily for most cases. Effectiveness of PPIs treatment requires knowledge of the mechanism gastric acid production, requirement of PPIs activation to bind the proton pump

and the reason of inactivation, also pharmacokinetics and pharmacodynamics of PPIs [4].

A clinical trial showed superiority of esomeprazole compared to lansoprazole for adults patients, but limited for pediatric cases [5]. This study focused to compare effectivity of Esomeprazole with lansoprazole for healing the symptoms of gastritis in pediatric patients.

## Methods

A randomized and single-blind (assessors) controlled trial was done at H. Adam Malik General hospital at Medan. This research followed the International Convention on Harmonization of Good Clinical Practice (ICH-GCP) and was approved by Health Research Ethical Committee Medical Faculty of Universitas Sumatera Utara/RSUP H. Adam Malik (under the ethics no: 145/KEP/USU/2020). All parents provided and approved informed consent and then randomization scheme with computer generated.

## Patients

Boy and girl children aged 2–18 year with symptoms that is abdominal pain, nausea, vomiting, haematemesis, or bloody stool and confirmed gastritis from gastroscopy. Patients with history of PPIs, H2 blockers, non steroid anti-inflammatory drugs (NSAIDs), dexamethasone usage within 14 days, any conditions that can affect gaster mucosa, and any digestive surgeries were excluded. Forty-eight patients were needed with 24 patients for each group for minimal samples.

## Study procedures

Patients that complied with to study's criteria and agreed to sign informed consent were collected information about the symptoms. After confirmation diagnosis of Gastritis by gastroscopy, then the patients randomized into two groups of treatment, the lansoprazole treatment group (15 mg if <30 kg and 30 mg if >30 kg) and esomeprazole treatment group (0,4–0,8 mg per kg body weight). Medication for both groups will be given orally for 14 days. After treatment, all the subjects were re-evaluated from initial symptoms. P-value of this study was calculated with the  $\chi^2$  test.

## Results

From total of 57 patients that fit the requirement and gastroscopy examination confirmed gastritis were 54 patients and all enrolled in this study; 27 patients received lansoprazole, and 27 patients received esomeprazole with 2 patients drop out. Two treatment groups have similar baseline characteristics and demographics (Table 1).

**Table 1: Baseline characteristics and demographic of patients evaluable for gastritis**

	Esomeprazole group (n = 25)	Lansoprazole group (n = 27)
Gender		
Male	9	8
Female	16	19
Age (year)	13.4 (5.1)	13.1 (5.3)
Weight (kg)	67.2 (18.6)	67.5 (18.2)
Height (cm)	141.1 (15.7)	139.8 (15.9)
Nutritional status		
Overweight	7	10
Good	11	9
Underweight	7	8
Malnutrition	0	0
Family history		
With Gastritis	19	23
Without Gastritis	6	4
Clinical symptoms		
Abdominal pain	12	17
Vomiting	5	5
Haematemesis	5	5
Nausea	3	0
Black and tarry stool	0	0

## Effectivity

Lansoprazole group after 14 days treatment showed that 5 patients (18.5%) from 27 patients

compared to esomeprazole group showed that 8 patients (32%) from 25 patients still have persistent initial symptoms (Table 2). Chi-square analysis using a computer program showed no significance between the two groups ( $p = 0.262$ ).

**Table 2: Comparison effectiveness between esomeprazole and lansoprazole**

Treatment	Symptoms after treatment		p
	Yes (%)	No (%)	
Lansoprazole	5 (18.5)	22 (81.5)	0.262 <sup>a</sup>
Esomeprazole	8 (32)	17 (68)	
Total	13	39	

<sup>a</sup>Pearson chi-square

From Table 3, lansoprazole and esomeprazole administration for 14 days have same effectivity in treating gastritis symptoms except abdominal pain. Lansoprazole groups has 88.24% free of abdominal pain compared to esomeprazole group for only 66.67% free of abdominal pain.

**Table 3: Effectiveness of esomeprazole and lansoprazole for each symptom**

Symptoms	Lansoprazole		Esomeprazole	
	Persistent (%)	Recovery (%)	Persisten (%)	Recovery (%)
Abdominal pain	2 (11.76)	15 (88.24)	4 (33.33)	8 (66.67)
Vomiting	1 (20)	4 (80)	1 (20)	4 (80)
Haematemesis	2 (40)	3 (60)	2 (40)	3 (60)
Nausea	-	-	1 (33.33)	2 (66.67)

## Discussion

Gastritis is known as damage of gastric mucosa due to inflammatory reactions. Imbalance of defensive dan aggressive factors cause complex multifactor pathologic process, and this process depends on individual's cellular and humoral response. This study showed that the incidence of gastritis between females and males is 67.3% and 32.7% or 2:1. Studies showed that gastritis incidence in pediatric between female and male were quite similar [6], [7].

Based on age, the incidence of gastritis in this study was dominated by 13–15.9 years group patients that is 24 patients (46.1%). The median age of patients with gastritis in this study was 13.5 years with ranging from 2.6 year to 17.7 year. Epidemiology studies also showed a similar result. A study from Japan showed the mean age of gastritis incidence in pediatric was  $11.3 \pm 3.4$  years for non-nodular gastritis and  $12.7 \pm 2.7$  years for nodular gastritis [6]. Other study showed that age between 11 and 12 years has gastritis incidence till 63% [8].

This study showed that incidence of gastritis is most commonly from a family with a history of gastritis. Incidence of gastritis from family with history of gastritis were 42 children or 80.8% compared with 10 children or 19.2% without family history of gastritis. Other study showed that family with history of gastritis caused mainly by *Helicobacter pylori* as major predisposition

factors. This proved that history taking of family history is one of the important informations to be asked during the examination [8].

Clinical symptoms from this study were dominated by abdominal pain (55.8%) followed by vomiting and hematemesis (respectively 19.2%). Research by Boukthir *et al.* to study prevalence and characteristics of pediatric chronic gastritis showed that the most common symptom is recurrent abdominal pain (67.4%) followed by vomiting (19.5%) and upper gastrointestinal bleeding (18.6%) [9]. Research by Kato *et al.* also showed that the most common symptom of pediatric gastritis in Japan was also abdominal pain followed by vomiting [6].

There is a study showed that obesity in children have higher chance to suffer gastroesophageal reflux disease (GERD) [10]. The only studies of PPI pharmacokinetics in obesity children were pantoprazole. Suggestion of those studies were used lean-body-weight-based (LBW) than total body weight (TBW) in calculate dosage of pantoprazole because obese children need lower doses [11], [12]. Long-term usage of PPI decreased uptake of micronutrients that need low pH such as vitamin B12, vitamin C, iron, calcium, magnesium, zinc, and  $\beta$ -carotene [13].

There is not any yet comparison study of effectivity between esomeprazole and lansoprazole in pediatric, however in adult patients still a controversy. A study by Fennerty *et al.* and Castell *et al.* that compared esomeprazole with lansoprazole in adult patients with moderate to severe erosive esophagitis showed that esomeprazole significantly more effective in time to healing and symptoms resolved [14], [15]. However, multicenter research by Chey *et al.* that compared esomeprazole 40 mg with lansoprazole 30 mg for gastro-esofagela reflux disease (GERD) showed no significant difference between two groups in resolving the symptoms [16]. Similar to this study's result that showed no significant difference between the two groups treatment ( $p = 0.262$ ).

This study showed lansoprazole and esomeprazole were effective for gastritis treatment. Similar to study by Faure *et al.* with cure rate 80% for 23 pediatric patients with reflux esophagitis that treated lansoprazole for 14 days and only 3 patients have side effect [17]. Multicenter dan randomized clinical trial by Gilger *et al.* showed that esomeprazole treatment for pediatric patients has effectivity almost 91.4% with side effect rate only 9.3% [18].

## Conclusion

This study showed no significant difference between lansoprazole and esomeprazole treatment for pediatric with gastritis in terms of healing time and

symptoms resolved. However, further randomized clinical trial and multicenter studies are suggested.

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