

# Lansoprazole Plus Levosulpiride Versus Esomeprazole In Participants With Gastroesophageal Reflux Disease And Erosive Esophagitis: A Double Blinded Randomized Control Trial

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## Introduction

- Dyspepsia is described as a complex of many symptoms referred to the gastroduodenal region of the gastrointestinal tract. It includes epigastric burning or pain, postprandial fullness, or early satiety.

## Objectives

- Our study aims at comparing the efficacy and safety of Lansoprazole plus Levosulpiride over Esomeprazole.

## Design/Methods

- This randomized control trial recruited 1000 participants having symptomatic gastroesophageal reflux disease (GERD) and erosive esophagitis and they were blindly randomized into two groups in a 1:1 ratio with appropriate concealment.
- Group 1 was given lansoprazole plus levosulpiride combination twice daily whereas group 2 was prescribed only esomeprazole twice daily.
- The primary efficacy endpoint was the healing of erosive esophagitis and GERD at week 49. Secondary assessments included improvement in quality of life. Participants' quality of life was assessed before starting the treatment and post-treatment using a short-form health survey questionnaire (SF-36).

## Results

- Our results showed the lansoprazole plus levosulpiride group had significantly lower rates of positive postintervention GERD and erosive esophagitis status, and higher rates of sustained resolution of heartburn compared to the esomeprazole alone group.
- However, the lansoprazole plus levosulpiride group also had a higher risk of nausea.

Post-intervention Erosive esophagitis status	Positive	Group		
		Lansoprazole plus levosulpiride	Esomeprazole alone	p-value
	10.2%	79.4%		
	Negative	89.8%	20.6%	
	Value	95% Confidence Interval Lower	Upper	
<b>Odds Ratio for post-intervention erosive esophagitis in lansoprazole plus levosulpiride group compared to esomeprazole alone group</b>				
	0.029	0.021	0.042	<0.01
<b>Relative risk for a positive post-intervention erosive esophagitis status in the lansoprazole plus levosulpiride group</b>				
	0.140	0.108	0.182	<0.01
<b>Relative risk for a positive post-intervention erosive esophagitis status in the esomeprazole alone group</b>				
	4.749	3.978	5.670	<0.01
<b>Mantel-Haenszel Common Odds Ratio Estimate</b>				
				0.029
<b>In (Estimate)</b>				
				-3.524
<b>p-value</b>				
				<0.01
<b>Asymptotic 95% Confidence Interval</b>				
		Common Odds Ratio	Lower Bound	0.021
			Upper Bound	0.042

## Independent samples T-test

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	p-value	t	df	p-value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Post-intervention GERD status	90.219	<0.01	30.602	998	<0.01	0.692	0.023	0.648	0.736
Quality of life post-intervention	96.197	<0.01	30.493	998	<0.01	2.660	0.087	2.489	2.831
Post-intervention Erosive esophagitis status	90.219	<0.01	30.602	998	<0.01	0.692	0.023	0.648	0.736

- The Lansoprazole plus Levosulpiride group showed a significantly lower percentage of participants with a positive post-intervention erosive esophagitis status compared to the Esomeprazole alone group (10.2% vs. 79.4%).
- The odds ratio for a positive post-intervention esophagitis status was 0.029, with a relative risk of 0.140. This suggests a significant difference between the two treatment groups.

## Conclusion

- Lansoprazole plus levosulpiride is a **more effective and safe treatment** for GERD than esomeprazole alone.
- Participants in the **lansoprazole plus levosulpiride group** showed a **significantly higher rate of sustained resolution of GERD**, lower rates of postintervention GERD and erosive esophagitis status, and a higher incidence of nausea compared to the esomeprazole alone group.
- Although quality of life worsened in both groups, adverse effects did not significantly differ.
- These findings **strongly support the use of lansoprazole plus levosulpiride** as a **preferred treatment option** for GERD and **erosive esophagitis**, which could have **significant clinical implications** for managing this common condition.

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