
Single Patient Drug Trial Comparing Two Acid Suppression Agents for Maintenance of Healing of Erosive Esophagitis - GERD

Guidance

Prevacid (lansoprazole) 30 mg daily is the suggested treatment for this patient, as compared to omeprazole 20 mg daily. Lansoprazole had a significantly lower incidence of "lower stomach pain" than omeprazole (17% of reported days vs. 67%, respectively). Although only 24 out of 72 days of the study were reported, the data were discriminating. Both treatments appeared to be effective as measured by high incidences of symptom-free and drug rescue-free treatment days.

Nature of Single-Patient Drug Trial

This was a double-blinded, randomized, 3 paired-period multiple-crossover study comparing Lansoprazole 30 mg qd to Omeprazole 20 mg qd each taken for 12 days at a time. Significance is shown for the single patient test when population data feedback is applied. The purpose of the test was to generate data on the comparative effectiveness and adverse event profile of these two test conditions to guide future treatment.

Summary of Findings

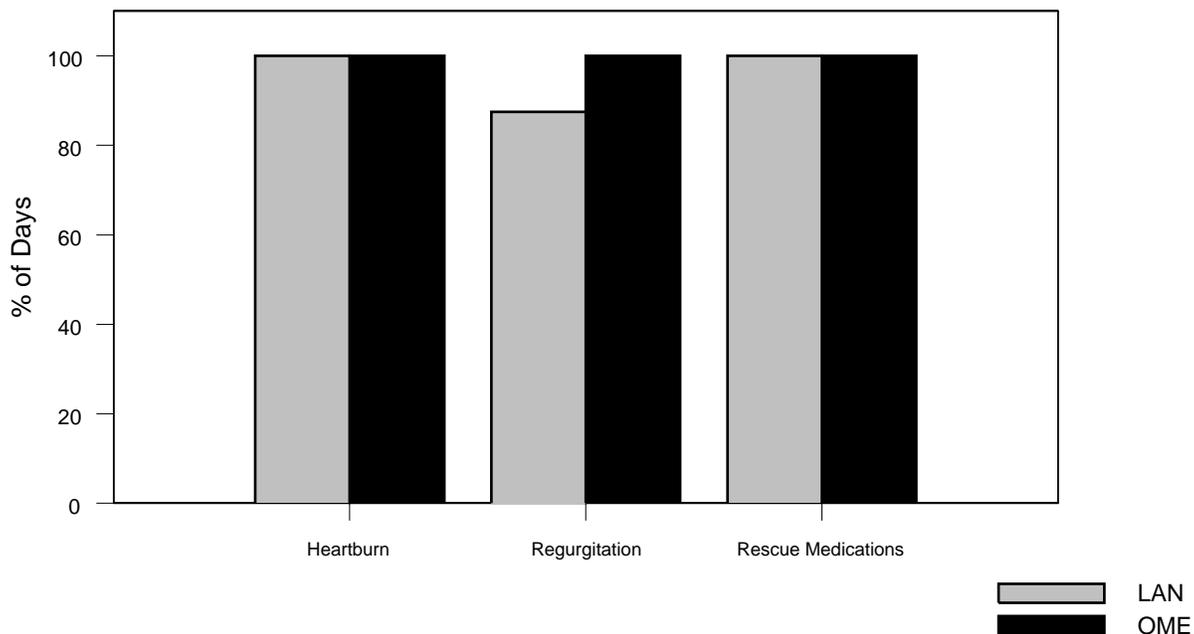
Effectiveness

No significant treatment difference in *Heartburn*.
No significant treatment difference in *Regurgitation*.
No significant treatment difference in *Rescue Medications*.
Insufficient data for analysis of *Patient Global Score*.

Solicited Adverse Events

No significant treatment difference in *Headache*.
No significant treatment difference in *Rash*.
No significant treatment difference in *Diarrhea*.
Lansoprazole had significantly lower incidence than **Omeprazole** in *Lower Stomach Pain*.
No significant treatment difference in *Nausea*.
No significant treatment difference in *Vomiting*.
No significant treatment difference in *Constipation*.
No significant treatment difference in *Bloating*.
No significant treatment difference in *Excess Gas*.

1. PERCENTAGE OF SYMPTOM & RESCUE-FREE DAYS¹



Treatment Comparisons

	LAN	OME	
Heartburn	100.0%	100.0%	P = 1.000 (Not statistically significant)
Regurgitation	87.5%	100.0%	P = 0.302 (Not statistically significant)
Rescue Medications	100.0%	100.0%	P = 1.000 (Not statistically significant)

Note: Number of Days Analyzed: 8 for LAN; 8 for OME.

1. For Days 5-12 in treatment period. Days 1-4 excluded due to possible carryover effects

Treatment Key: LAN = Lansoprazole OME = Omeprazole

Kit ID: 0207001019

Kit Type: 02007

Date of Report: May 22, 2004

2. PATIENT GLOBAL RATING¹

**** INSUFFICIENT DATA FOR ANALYSIS ****

Treatment Key: LAN = Lansoprazole OME = Omeprazole

ADVERSE EVENT RESULTS

1. SOLICITED ADVERSE EVENTS

Treatment Comparisons: Percentage of Days an Adverse Event was Reported

	LAN	OME	
Headache	33.3%	50.0%	P = 0.680 (Not statistically significant)
Rash	0.0%	0.0%	P = 1.000 (Not statistically significant)
Diarrhea	16.7%	50.0%	P = 0.193 (Not statistically significant)
Lower Stomach Pain	16.7%	66.7%	P = 0.036 * (statistically significant)
Nausea	0.0%	0.0%	P = 1.000 (Not statistically significant)
Vomiting	0.0%	0.0%	P = 1.000 (Not statistically significant)
Constipation	0.0%	0.0%	P = 1.000 (Not statistically significant)
Bloating	0.0%	0.0%	P = 1.000 (Not statistically significant)
Excess Gas	0.0%	0.0%	P = 1.000 (Not statistically significant)

Note: Number of Days Analyzed: 12 for LAN; 12 for OME.

2. VOLUNTEERED ADVERSE EVENTS

- none -

Treatment Key: LAN = Lansoprazole OME = Omeprazole

Notes - Effectiveness Analyses:

P-value for *Patient Global Rating* were computed on the basis of paired t-tests, using a pooled variance estimate that incorporated results from Opt-e-scrip's database of single patient trials comparing these treatments in the relevant patient population. P-values for *percentage of symptom-free days* for individual symptoms were calculated using the chi-square test. All tests were performed at $\alpha = 0.10$ for the two-tailed alternative hypothesis. Analyses of effectiveness were based on the data for days 5 through 12 of each period. Data for the days 1 through 4 of each period was excluded to insure that the outcome was minimally affected by the treatment administered during the previous period (i.e. carryover effects). This method was validated in a series of prior, similar trials. The power of this test to detect a 2 point (20%) difference in Patient Global Rating is approximately 90%. For percentage of symptom-free days, these tests have power of up to 80% to detect a treatment difference of 25%.

Notes – Adverse Events Analyses:

P-values were computed on the basis of Fisher's Exact Test, treating all daily responses as independent observations. Although this assumption may not be fully justified, the inherently conservative nature of this test will result in p-values that provide a reasonable basis for making cautious decisions. This statistical approach maximizes the likelihood of identifying a significant difference in adverse event incidence when a real difference exists. Tests were performed at $\alpha = 0.10$ for two-tailed alternative hypotheses. These tests have power of approximately 80% to detect a treatment difference of 20%.