Efficacy and Safety of Dexlansoprazole MR and Lansoprazole on Healing of Erosive Esophagitis

This study has been completed.

Sponsor:
Takeda

Information provided by (Responsible Party):
Takeda

ClinicalTrials.gov Identifier:
NCT00251693

First received: November 8, 2005
Last updated: February 1, 2012
Last verified: February 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: February 20, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Esophagitis, Reflux Esophagitis, Peptic
Interventions:	Drug: Dexlansoprazole MR Drug: Lansoprazole

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Subjects were enrolled at 95 sites in the United States (US) and 55 ex-US sites from 02 December 2005 to 30 January 2007.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Subjects recorded day and nighttime heartburn symptoms and rescue medications for a screening period of up to 21 days. Subjects with endoscopically-proven erosive esophagitis (EE) at screening were enrolled in Dexlansoprazole Modified Release (MR) or Lansoprazole once daily (QD) treatment group.

Reporting Groups

	Description
Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 8 weeks.
Dexlansoprazole MR 90 mg QD	Dexlansoprazole MR 90 mg, capsules, orally, once daily for up to 8 weeks.
Lansoprazole 30 mg QD	Lansoprazole 30 mg, capsules, orally, once daily for up to 8 weeks.

Participant Flow: Overall Study

	Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 90 mg QD	Lansoprazole 30 mg QD
STARTED	**680**	**668**	**690**
COMPLETED	**629**	**624**	**644**
NOT COMPLETED	**51**	**44**	**46**
Adverse Event	**17**	**9**	**9**
Protocol Violation	**2**	**0**	**2**
Lost to Follow-up	**12**	**7**	**8**
Withdrawal by Subject	**11**	**17**	**14**
Lack of Efficacy	**0**	**1**	**0**
Inclusion/exclusion criteria not met	**5**	**3**	**8**
Noncompliant	**0**	**0**	**2**
Possible Barrett's esophagus	**3**	**5**	**2**
Subject request/subject unavailable	**1**	**2**	**0**
Abnormal laboratory findings	**0**	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
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Reporting Groups

	Description
Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 8 weeks.
Dexlansoprazole MR 90 mg QD	Dexlansoprazole MR 90 mg, capsules, orally, once daily for up to 8 weeks.
Lansoprazole 30 mg QD	Lansoprazole 30 mg, capsules, orally, once daily for up to 8 weeks.
Total	Total of all reporting groups

Baseline Measures

	Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 90 mg QD	Lansoprazole 30 mg QD	Total
Number of Participants	**680**	**668**	**690**	**2038**

[units: participants]				
Age, Customized [units: participants]				
<45 Years	**269**	**276**	**288**	**833**
45 Years to <65 Years	**349**	**328**	**332**	**1009**
>=65 Years	**62**	**64**	**70**	**196**
Age [units: years] Mean (Standard Deviation)	**47.8 (13.71)**	**47.3 (13.93)**	**47.3 (13.74)**	**47.5 (13.79)**
Gender [units: participants]				
Female	**300**	**302**	**325**	**927**
Male	**380**	**366**	**365**	**1111**
Ethnicity (NIH/OMB) [units: participants]				
Hispanic or Latino	**60**	**52**	**54**	**166**
Not Hispanic or Latino	**620**	**616**	**636**	**1872**
Unknown or Not Reported	**0**	**0**	**0**	**0**
Race (NIH/OMB) [units: participants]				
American Indian or Alaska Native	**6**	**4**	**7**	**17**
Asian	**27**	**33**	**33**	**93**
Native Hawaiian or Other Pacific Islander	**1**	**0**	**1**	**2**
Black or African American	**32**	**33**	**27**	**92**
White	**602**	**580**	**601**	**1783**
More than one race	**10**	**15**	**17**	**42**
Unknown or Not Reported	**2**	**3**	**4**	**9**
Los Angeles (LA) Classification Grade for Erosive Esophagitis (EE) [1] [units: Paricipants]				
A: ≥1 mucosal break <5mm	**236**	**242**	**231**	**709**
B: ≥1 mucosal break ≥5mm	**247**	**233**	**248**	**728**
C: ≥1 mucosal break and <75% of the circumference	**163**	**148**	**170**	**481**
D: ≥1 mucosal break and ≥75% of the circumference	**33**	**45**	**40**	**118**
Not Applicable	**1**	**0**	**1**	**2**

[1] LA Classification for Esophagitis Grading System (grades A, B, C, D) with increasing severity from grade A to grade D.

Outcome Measures

Show All Outcome Measures

1. Primary: Percentage of Subjects With Complete Healing of Erosive Esophagitis (EE) by Week 8 as Assessed by Endoscopy - Crude Rate Analysis. [Time Frame: 8 Weeks]

Show Outcome Measure 1

2. Primary: Percentage of Subjects With Complete Healing of Erosive Esophagitis by Week 8 as Assessed by Endoscopy - Life Table Method. [Time Frame: 8 weeks]

Show Outcome Measure 2

3. Secondary: Percentage of Subjects With Baseline Erosive Esophagitis Grade C or D Combined Who Have Complete Healing of Erosive Esophagitis by Week 8 as Assessed by Endoscopy - Crude Rate Analysis. [Time Frame: 8 Weeks]

Show Outcome Measure 3

4. Secondary: Percentage of Subjects With Baseline Erosive Esophagitis Grade C or D Combined Who Have Complete Healing of Erosive Esophagitis by Week 8 as Assessed by Endoscopy - Life Table Method. [Time Frame: 8 Weeks]

Show Outcome Measure 4

5. Secondary: Percentage of Subjects With Complete Healing of Erosive Esophagitis by Week 4 as Assessed by Endoscopy - Crude Rate Analyses. [Time Frame: 4 Weeks]

Show Outcome Measure 5

6. Secondary: Percentage of Subjects With Complete Healing of Erosive Esophagitis by Week 4 as Assessed by Endoscopy - Life Table Method. [Time Frame: 4 Weeks]

Show Outcome Measure 6

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
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More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor

☐ cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** No publication related to study results will be published prior to publication of a multi-center report submitted for publication within 18 months after conclusion or termination of a study. Results publications will be submitted to sponsor for review 60 days in advance of publication. Sponsor can require removal of confidential information unrelated to study results. Sponsor can embargo a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact:

Name/Title: Sr. VP Clinical Sciences
Organization: Takeda Global Research and Development Center, Inc.
phone: 800-778-2860
e-mail: clinicaltrialregistry@tpna.com

Publications of Results:

Sharma P, Shaheen NJ, Perez MC, Pilmer BL, Lee M, Atkinson SN, Peura D. Clinical trials: healing of erosive oesophagitis with dexlansoprazole MR, a proton pump inhibitor with a novel dual delayed-release formulation--results from two randomized controlled studies. Aliment Pharmacol Ther. 2009 Apr 1;29(7):731-41. doi: 10.1111/j.1365-2036.2009.03933.x.

Peura DA, Metz DC, Dabholkar AH, Paris MM, Yu P, Atkinson SN. Safety profile of dexlansoprazole MR, a proton pump inhibitor with a novel dual delayed release formulation: global clinical trial experience. Aliment Pharmacol Ther. 2009 Nov 15;30(10):1010-21. doi: 10.1111/j.1365-2036.2009.04137.x. Epub 2009 Sep 4.

Wyrwich KW, Mody R, Larsen LM, Lee M, Harnam N, Revicki DA. Validation of the PAGI-SYM and PAGI-QOL among healing and maintenance of erosive esophagitis clinical trial participants. Qual Life Res. 2010 May;19(4):551-64. doi: 10.1007/s11136-010-9620-x. Epub 2010 Feb 27.

Friedlander EA, Pallentino J, Miller SK, VanBeuge SS. The evolution of proton pump inhibitors for the treatment of gastroesophageal reflux disease. J Am Acad Nurse Pract. 2010 Dec;22(12):674-83. doi: 10.1111/j.1745-7599.2010.00578.x. Epub 2010 Nov 24. Review.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Peura DA, Pilmer B, Hunt B, Mody R, Perez MC. Distinguishing the impact of dexlansoprazole on heartburn vs. regurgitation in patients with gastro-oesophageal reflux disease. Aliment Pharmacol Ther. 2013 Nov;38(10):1303-11. doi: 10.1111/apt.12504. Epub 2013 Sep 30.

Peura DA, Pilmer B, Hunt B, Mody R, Perez MC. The effects of increasing body mass index on heartburn severity, frequency and response to treatment with dexlansoprazole or lansoprazole. Aliment Pharmacol Ther. 2013 Apr;37(8):810-8. doi: 10.1111/apt.12270. Epub 2013 Mar 4.

Responsible Party:	Takeda
ClinicalTrials.gov Identifier:	NCT00251693 History of Changes
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Health Authority:	United States: Food and Drug Administration

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