Comparison of Dexlansoprazole MR to Placebo on the Ability to Maintain Healing in Subjects With Healed Erosive Esophagitis

This study has been completed.

Sponsor:
Takeda

Information provided by (Responsible Party):
Takeda

ClinicalTrials.gov Identifier:
NCT00255151

First received: November 15, 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: Placebo

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 105 sites in the United States; date of first dose (04 January 2006; date of last procedure: 14 November 2006).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Subjects had to have endoscopically proven healed erosive esophagitis (EE) after 4 to 8 weeks of treatment with lansoprazole 30 mg once-daily (QD), dexlansoprazole modified release (MR) 60 mg QD, or dexlansoprazole MR 90 mg QD in the EE healing studies, T-EE04-084 (NCT00251693) and T-EE04-085 (NCT00251719).

Reporting Groups

	Description
Placebo QD	Placebo capsules, orally, once daily for up to 6 months.
Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Dexlansoprazole MR 90 mg QD	Dexlansoprazole MR 90 mg, capsules, orally, once daily for up to 6 months.

Participant Flow: Overall Study

	Placebo QD	Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 90 mg QD
STARTED	**140**	**159**	**152**
COMPLETED	**17**	**110**	**103**
NOT COMPLETED	**123**	**49**	**49**
Adverse Event	**10**	**6**	**9**
Lost to Follow-up	**4**	**3**	**4**
Withdrawal by Subject	**18**	**17**	**8**
Noncompliance	**0**	**1**	**2**
Subject Request/Subject Unavailable	**1**	**1**	**2**
Relapse of Erosive Esophagitis	**78**	**16**	**12**
Possible Barrett's Esophagus	**1**	**3**	**8**
Esophageal Stricture	**0**	**0**	**1**
Therapeutic Failure	**11**	**2**	**3**

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.
No text entered.

Reporting Groups

	Description
Placebo QD	Placebo capsules, orally, once daily for up to 6 months.
Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Dexlansoprazole MR 90 mg QD	Dexlansoprazole MR 90 mg, capsules, orally, once daily for up to 6 months.
Total	Total of all reporting groups

Baseline Measures

	Placebo QD	Dexlansoprazole MR 60 mg QD	Dexlansoprazole MR 90 mg QD	Total
Number of Participants [units: participants]	**140**	**159**	**152**	**451**
Age				

[units: years] Mean (Standard Deviation)	**48.2 (12.88)**	**49.7 (12.66)**	**48.8 (13.76)**	**48.9 (13.09)**
Age, Customized [units: participants]				
<45 years	**48**	**55**	**56**	**159**
45 to <65 years	**81**	**86**	**81**	**248**
≥65 years	**11**	**18**	**15**	**44**
Gender [units: participants]				
Female	**70**	**76**	**70**	**216**
Male	**70**	**83**	**82**	**235**
Race (NIH/OMB) [units: participants]				
American Indian or Alaska Native	**2**	**2**	**1**	**5**
Asian	**2**	**3**	**0**	**5**
Native Hawaiian or Other Pacific Islander	**0**	**0**	**0**	**0**
Black or African American	**11**	**17**	**11**	**39**
White	**124**	**135**	**136**	**395**
More than one race	**1**	**2**	**4**	**7**
Unknown or Not Reported	**0**	**0**	**0**	**0**
Ethnicity (NIH/OMB) [units: participants]				
Hispanic or Latino	**15**	**19**	**14**	**48**
Not Hispanic or Latino	**125**	**140**	**138**	**403**
Unknown or Not Reported	**0**	**0**	**0**	**0**
Baseline Los Angeles (LA) Classification Grade for Erosive Esophagitis (EE) [1] [units: participants]				
A: ≥1 mucosal break <5 mm	**58**	**60**	**54**	**172**
B: ≥1 mucosal break ≥5 mm	**48**	**61**	**58**	**167**
C: ≥1 mucosal break <75% of circumference	**28**	**33**	**32**	**93**
D: ≥1 mucosal break ≥75% of circumference	**6**	**5**	**8**	**19**

[1] Baseline values from Studies T-EE04-084 (NCT00251693)and T-EE04-085 (NCT00251719), with severity of EE increasing from Grade A to Grade D.

Outcome Measures

Show All Outcome Measures

1. Primary: Percentage of Subjects Who Maintained Complete Healing of Erosive Esophagitis as Assessed by Endoscopy - Crude Rate Analysis. [Time Frame: 6 months]

Show Outcome Measure 1

2. Primary: Percentage of Subjects Who Maintained Complete Healing of Erosive Esophagitis as Assessed by Endoscopy - Life Table Method [Time Frame: 6 months]

Show Outcome Measure 2

3. Secondary: Percentage of Days Without Daytime or Nighttime Heartburn as Assessed by Daily Diary-Median. [Time Frame: 6 months]

Show Outcome Measure 3

4. Secondary: Percentage of Days Without Daytime or Nighttime Heartburn as Assessed by Daily Diary-Mean. [Time Frame: 6 months]

Show Outcome Measure 4

5. Secondary: Percentage of Days Without Nighttime Heartburn as Assessed by Daily Diary-Median. [Time Frame: 6 months]

Show Outcome Measure 5

6. Secondary: Percentage of Days Without Nighttime Heartburn as Assessed by Daily Diary-Mean. [Time Frame: 6 months]

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
No text entered.

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:

Howden CW, Larsen LM, Perez MC, Palmer R, Atkinson SN. Clinical trial: efficacy and safety of dexlansoprazole MR 60 and 90 mg in healed erosive oesophagitis - maintenance of healing and symptom relief. Aliment Pharmacol Ther. 2009 Nov 1;30(9):895-907. doi: 10.1111/j.1365-2036.2009.04119.x. Epub 2009 Aug 14.

Responsible Party:	Takeda
ClinicalTrials.gov Identifier:	NCT00255151 History of Changes
Other Study ID Numbers:	**T-EE04-087**
	U1111-1114-1767 (Registry Identifier: WHO)
Study First Received:	November 15, 2005
Results First Received:	February 20, 2009
Last Updated:	February 1, 2012
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK