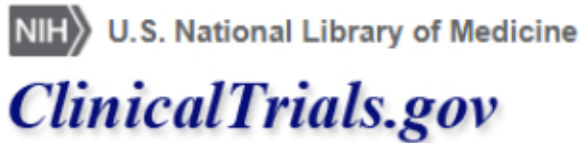


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Trial record **1 of 1** for: NCT01459367

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Efficacy of TAK-438 Compared to AG-1749 (Lansoprazole) in the Maintenance Treatment of Healed Erosive Esophagitis

This study has been completed.

Sponsor:


Takeda

ClinicalTrials.gov Identifier:

NCT01459367

First Posted: October 25, 2011

Last Update Posted: August 23, 2013

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Information provided by (Responsible Party):

Takeda

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[No Study Results Posted](#)

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Purpose

The purpose of this study is to confirm the efficacy of TAK-438, once daily (QD), compared to lansoprazole for the maintenance treatment of healed erosive esophagitis and to determine the clinical dose.

Condition	Intervention	Phase

Erosive Esophagitis	Drug: TAK-438 Drug: Lansoprazole	Phase 3
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Study Type: Interventional

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy and Safety of TAK-438 (10 mg or 20 mg Once-Daily) Compared to AG-1749 (15 mg Once-Daily) in a 24-week Maintenance Treatment in Patients With Healed Erosive Esophagitis (EE).

Resource links provided by NLM:

[Drug Information](#) available for: [Lansoprazole](#) [Dexlansoprazole](#)

[U.S. FDA Resources](#)

Further study details as provided by Takeda:

Primary Outcome Measures:

- Endoscopically confirmed recurrence rate of erosive esophagitis after 24 weeks of maintenance treatment [Time Frame: 24 Weeks.]

Endoscopic recurrence of erosive esophagitis is defined as those participants who have endoscopically confirmed EE of Grade A to D as defined by the Los Angeles (LA) Classification Grading System. The definitions of each grade are: Grade O (No mucosal break), Grade A (Mucosal break <5 mm), Grade B (Mucosal break ≥5 mm), Grade C (Mucosal break continuous between two or more folds and <75% of the circumference) and Grade D (Mucosal break ≥75% of the circumference).

Secondary Outcome Measures:

- Endoscopically confirmed recurrence rate of erosive esophagitis after 12 weeks of maintenance treatment [Time Frame: 12 Weeks.]

Enrollment: 607

Study Start Date: October 2011

Study Completion Date: March 2013

Primary Completion Date: March 2013 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
Experimental: TAK-438 10 mg QD	<p>Drug: TAK-438</p> <p>In the treatment period, the participants will receive treatment of TAK-438 20 mg, tablets, orally, once daily for up to 8 weeks.</p> <p>In the maintenance treatment period, the participants will receive treatment of TAK-438 10 mg, tablets, orally, once daily and lansoprazole placebo-matching capsules, orally, once daily for up to 24 weeks.</p>
Experimental: TAK-438 20 mg QD	<p>Drug: TAK-438</p> <p>In the treatment period, the participants will receive treatment of TAK-438 20 mg, tablets, orally, once daily for up to 8 weeks.</p> <p>In the maintenance treatment period, the participants will receive treatment of TAK-438 20 mg, tablets, orally, once daily and lansoprazole placebo-matching capsules, orally, once daily for up to 24 weeks.</p>
Active Comparator: Lansoprazole 15 mg QD	<p>Drug: Lansoprazole</p> <p>In the treatment period, the participants will receive treatment of TAK-438 20 mg, tablets, orally, once daily for up to 8 weeks.</p> <p>In the maintenance treatment period, the participants will receive treatment of TAK-438 placebo-matching tablets, orally, once daily and lansoprazole 15 mg, capsules, orally, once daily for up to 24 weeks.</p> <p>Other Name: AG-1749</p>

Eligibility

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study

research staff using the contacts provided below. For general information, [Learn About Clinical Studies.](#)

Ages Eligible for Study: 20 Years and older (Adult, Senior)
 Sexes Eligible for Study: All
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. At Visit H-1 (start of the treatment period), the participants must have endoscopically confirmed erosive esophagitis of Grade A to D, as defined by the LA classification grading system, and the target number of participants who are clearly Grade C or D is 15% or more of the total participants.
2. Outpatients (including inpatient for examination)
3. Participants must have successfully completed the treatment period and have endoscopically healed EE at Week 2, 4, or 8 in the treatment period. Endoscopically healed EE is defined as those participants who have endoscopically confirmed EE of Grade O as defined by the LA classification grading system.

Exclusion Criteria:

1. Participants with an esophagus-related complication (eosinophilic esophagitis, esophageal varices, scleroderma, viral or fungal infection, esophageal stenosis, etc.), a history of radiotherapy or cryotherapy of the esophagus, a caustic or physiochemical trauma (esophageal sclerotherapy, etc.). However, participants with Schatzki's ring (mucosal tissue ring around inferior esophageal sphincter) or Barrett's esophagus are allowed to be included.
2. Participants who have received surgery or treatment affecting gastroesophageal reflux (cardioplasty, dilation of esophageal stenosis [excluding Schatzki's ring], etc.), or who have a history of surgery of stomach or duodenum (excluding removal of benign polyp under endoscopy)
3. Participants who have acute upper gastrointestinal bleeding, gastric or duodenal ulcer (mucosal defect with white coating) within 30 days prior to Visit H-1 (initiation of study drug administration). However, participants with gastric or duodenal erosions are allowed to be included.
4. Participants with a previous or current history of Zollinger-Ellison syndrome, or other gastric acid hypersecretion disorder

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):

NCT01459367

Locations**Japan**

Kashiwa-shi, Chiba, Japan
Yachiyo-shi, Chiba, Japan
Saijo-shi, Ehime, Japan
Fukuoka-shi, Fukuoka, Japan
Kasuya-gun, Fukuoka, Japan
Koriyama-shi, Fukushima, Japan
Takayama-shi, Gifu, Japan
Annaka-shi, Gunma, Japan
Asahikawa-shi, Hokkaido, Japan
Sapporo-shi, Hokkaido, Japan
Itami-shi, Hyogo, Japan
Kobe-shi, Hyogo, Japan
Nishinomiya-shi, Hyogo, Japan
Fujisawa-shi, Kanagawa, Japan
Yokohama-shi, Kanagawa, Japan
Kochi-shi, Kochi, Japan
Kumamoto-shi, Kumamoto, Japan
Kyoto-shi, Kyoto, Japan
Sendai-shi, Miyagi, Japan
Nagasaki-shi, Nagasaki, Japan
Kishiwada-shi, Osaka, Japan
Osaka-shi, Osaka, Japan
Suita-shi, Osaka, Japan
Takatsuki-shi, Osaka, Japan
Saga-shi, Saga, Japan
Kumagaya-shi, Saitama, Japan
Saitama-shi, Saitama, Japan
Tokorozawa-shi, Saitama, Japan
Bunkyo-ku, Tokyo, Japan

Chuo-ku, Tokyo, Japan
 Hachioji-shi, Tokyo, Japan
 Kokubunji-shi, Tokyo, Japan
 Shibuya-ku, Tokyo, Japan
 Shinjuku-ku, Tokyo, Japan
 Toshima-ku, Tokyo, Japan
 Shimonoseki-shi, Yamaguchi, Japan
 Tsuru-shi, Yamanashi, Japan

Sponsors and Collaborators

Takeda

Investigators

Study Director: Senior Manager Takeda

More Information

Responsible Party: Takeda
 ClinicalTrials.gov Identifier: [NCT01459367](#) [History of Changes](#)
 Other Study ID Numbers: TAK-438/CCT-003
 U1111-1125-1054 (Registry Identifier: WHO)
 JapicCTI-111662 (Registry Identifier: JapicCTI)
 First Submitted: October 24, 2011
 First Posted: October 25, 2011
 Last Update Posted: August 23, 2013
 Last Verified: August 2013

Keywords provided by Takeda:

Drug Therapy

Additional relevant MeSH terms:

Esophagitis	Dexlansoprazole
Esophageal Diseases	Anti-Ulcer Agents
Gastrointestinal Diseases	Gastrointestinal Agents
Digestive System Diseases	Proton Pump Inhibitors
Gastroenteritis	Enzyme Inhibitors
Lansoprazole	Molecular Mechanisms of Pharmacological Action