Trial record **1 of 1** for: NCT03736369

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Study to Evaluate the Efficacy and Safety of DWP14012 in Patients With Erosive Gastroesophageal Reflux Disease (Phase 3)

ClinicalTrials.gov Identifier: NCT03736369

Recruitment Status : Completed
First Posted : November 9, 2018
Last Update Posted : September 3, 2020

Sponsor:
Daewoong Pharmaceutical Co. LTD.

Information provided by (Responsible Party):
Daewoong Pharmaceutical Co. LTD.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:
The purpose of study is to confirm the efficacy of DWP14012 Xmg, Once daily, compared to esomeprazole 40mg in patients with erosive gastroesophageal reflux disease.

Condition or disease	Intervention/treatment	Phase

Erosive Esophagitis	Drug: DWP14012 40mg Drug: DWP14012 40mg placebo Drug: Esomeprazole 40mg Drug: Esomeprazole 40mg placebo	Phase 3

Study Design

Go to

Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
263 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

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

Primary Purpose:
Treatment

Official Title:
A Multi-Center, Randomized, Double-Blind, Active-controlled, Parallel-Group, Phase 3, Therapeutic Confirmatory Study to Evaluate the Efficacy and Safety of DWP14012 in Patients With Erosive Gastroesophageal Reflux Disease

Actual Study Start Date :
December 13, 2018

Actual Primary Completion Date :
August 7, 2019

Actual Study Completion Date :
August 7, 2019

Resource links provided by the National Library of Medicine

MedlinePlus related topics: GERD

Drug Information available for: Esomeprazole

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: DWP14012 40mg Orally, once daily	Drug: DWP14012 40mg DWP14012 40mg, tablet, orally, once daily for up to 8 weeks Drug: Esomeprazole 40mg placebo Esomeprazole 40mg placebo-matching tablet, orally, once daily for up to 8 weeks Other Name: Nexium 40mg placebo
Active Comparator: Esomeprazole 40mg Orally, once daily	Drug: DWP14012 40mg placebo DWP14012 40mg placebo-matching tablet, orally, once daily for up to 8 weeks Drug: Esomeprazole 40mg Esomeprazole 40mg tablet, orally, once daily for up to 8 weeks Other Name: Nexium 40mg

Outcome Measures

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Primary Outcome Measures :

1. Cumulative healing rate of erosive esophagitis at 8week by endoscopy [Time Frame: at 8week]

Secondary Outcome Measures :

1. Cumulative healing rate of erosive esophagitis at 4week by endoscopy [Time Frame: at 4week]
2. Reflux disease symptom assessment using RDQ(Reflux disease questionnaire) [Time Frame: at 4week and 8week]

   Mean change of the frequency or severity of main symptoms

3. Quality of Life assessment using GERD-HRQL(GERD-Health related quality life) [Time Frame: at 4week and 8week]

   Mean change of the total score of GERD-HRQL

Eligibility Criteria

Go to

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 to 75 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Adults between 20 and 75 years old based on the date of written agreement
- Those who have been diagnosed with erosive gastroesophageal reflux disease(EGRD) of LA Grade A-D on the upper gastrointestinal endoscopy
- Those who experienced symptoms of heartburn or acid regurgitation within the last 7 days

Exclusion Criteria:

- Those who have undergone gastric acid suppression or gastric, esophageal surgery
- Those who with clinically significant liver, kidney, nervous system, respiratory, endocrine, hematologic, cardiovascular, urinary system disease

Contacts and Locations

Go to

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): ***NCT03736369***

Locations

Korea, Republic of

Hanyang University Medical Center
Seoul, Korea, Republic of

Sponsors and Collaborators

Daewoong Pharmaceutical Co. LTD.

More Information

Go to

Responsible Party:
Daewoong Pharmaceutical Co. LTD.

ClinicalTrials.gov Identifier:
NCT03736369 History of Changes

Other Study ID Numbers:
DW_DWP14012301

First Posted:
November 9, 2018 Key Record Dates

Last Update Posted:
September 3, 2020

Last Verified:
September 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:
No

Studies a U.S. FDA-regulated Drug Product:
No

Studies a U.S. FDA-regulated Device Product:
No

Additional relevant MeSH terms:

Gastroesophageal Reflux
Esophagitis
Esophageal Motility Disorders
Deglutition Disorders
Esophageal Diseases
Gastrointestinal Diseases
Digestive System Diseases
Gastroenteritis
Esomeprazole
Anti-Ulcer Agents
Gastrointestinal Agents
Proton Pump Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action