

# Predictors of symptomatic response to pantoprazole in patients with laryngopharyngeal reflux

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<b>Registration date</b> 17/08/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/08/2016	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Gastroesophageal reflux disease (GERD) is a long-term condition where stomach acid comes up into the esophagus (gullet). It is usually caused when the ring of muscle at the bottom of the esophagus is weakened, leading to stomach acid easily being able to leak through. As well as causing heartburn and indigestion, this can lead to discomfort in the throat, hoarseness or voice loss, and cough (laryngeal symptoms) because the stomach acid gradually causes damage to the esophagus. A common treatment for this is a medication called pantoprazole, which decreases the amount of acid produced by the stomach, coupled with lifestyle modifications such as not eating late at night and weight loss. This treatment is generally effective, but it does not work for all patients. This study is going to look at patients suffering from laryngeal symptoms because of GERD (laryngopharyngeal reflux). The aim of this study is to find out whether there are any signs that may be able to predict whether a patient with laryngopharyngeal reflux will respond to pantoprazole and lifestyle modification treatment.

### Who can participate?

Adults complaining of hoarseness, sore throat, throat burning/pain, throat clearing, voice loss, cough, excessive throat mucus, globus (feeling of having something stuck in the throat), or choking for at least four weeks in the last three months.

### What does the study involve?

All participants are prescribed 40mg pantoprazole to take 30-60 minutes before breakfast and dinner for 12 weeks, and information about how they can change their lifestyle to improve their symptoms. Participants are invited to answer three questionnaires ("Reflux Symptom Index" designed to test for signs of laryngopharyngeal reflux, "GerdQ" developed as a diagnostic tool for GERD patients visiting their doctor about upper GI (esophagus, stomach and first part of the intestine) complaints and "An ad hoc questionnaire" designed by the research team to investigate other possible causes of laryngeal irritation) and laryngoscopy exam (examination of the back of the throat) at the start of the study and then again after four and 12 weeks.

What are the possible benefits and risks of participating?  
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?  
Hospital Alemán (Argentina)

When is the study starting and how long is it expected to run for?  
December 2015 to May 2018

Who is funding the study?  
Takeda Pharmaceuticals U.S.A. (USA)

Who is the main contact?  
Dr Pablo Luna

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Pablo Luna

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1118

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
IISR-2014-100849

## Study information

**Scientific Title**  
Clinical and laryngoscopic predictors of symptomatic response to pantoprazole magnesium in patients with newly diagnosed laryngopharyngeal reflux: a prospective study

**Study objectives**

There are certain clinical and laryngoscopic features that may predict response to PPI therapy (pantoprazole magnesium) in patients with suspected laryngopharyngeal reflux.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Comité de ética independiente Hospital Alemán (Argentina), 18/07/2016, ref: 172

**Study design**

Prospective observational cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Laryngopharyngeal reflux

**Interventions**

All participants are receiving pantoprazole magnesium 40 mg (Tecta R) one capsule given orally 30-60 minutes before breakfast and dinner for 12 weeks and education about lifestyle modifications (avoid late-night meals or eating 2-3 hours before bedtime, head of bed elevation for patients with nocturnal symptoms) and weight loss (for patients who are overweight or or have recently gained weight). as part of their standard care.

On day one of the study, patients evaluated in the otolaryngology unit with laryngopharyngeal reflux symptoms and meet the inclusion criteria will be invited to participate. Following provision of informed consent, patients are required to answer three questionnaires (Reflux symptom index – RSI, GerdQ questionnaire and an ad hoc questionnaire designed by the research team to investigate other possible etiologies of laryngeal irritation). Laryngoscopy, Reflux finding score (RFS) and retro laryngeal reflux score (proposed by the team) will be assessed as standard diagnostic evaluation. An upper gastrointestinal endoscopy will be performed only if patients present frequent typical reflux symptoms (> 2 per week). Los Angeles classification will be used for grading of reflux esophagitis.

After 4 weeks, an Interim Symptom evaluation will be performed (RSI and GerdQ questionnaire will be repeated) and pantoprazole treatment adherence will be evaluated in Gastroenterology unit.

After 12 weeks, patients are re-evaluated in the otolaryngology unit with RSI, GerdQ, and laryngoscopy (RFS and retro laryngeal score).

## **Intervention Type**

### **Primary outcome measure**

Proportion of patients responding to pantoprazole magnesium treatment is determined using Reflux Proportion of patients responding to pantoprazole magnesium treatment is determined using the Reflux symptom index (RSI), GerdQ questionnaire, Laryngoscopy, Reflux finding score (RFS) and retro laryngeal reflux score at baseline, 4 and 12 weeks.

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

08/12/2015

### **Completion date**

31/05/2018

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years and over
2. Chief complaint of hoarseness, sore throat, throat burning/pain, throat clearing, voice loss, cough, excessive throat mucus, globus, or choking for at least 4 weeks in the preceding 3 months

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

100

### **Key exclusion criteria**

1. Patients younger than age 18
2. Patients with identifiable laryngeal pathology
3. Upper respiratory tract infection in the past 4 weeks

4. Identifiable allergic causes of laryngitis
5. Previous laryngeal malignancy, surgery or radiotherapy
6. Women of childbearing potential not using an effective contraceptive method
7. Acid-suppressive therapy within the past 4 weeks
8. Hypersensitivity to the active ingredient, or to any of the excipients of the product
9. Patients taking HIV protease inhibitors or methotrexate

**Date of first enrolment**

01/09/2016

**Date of final enrolment**

31/12/2017

## **Locations**

**Countries of recruitment**

Argentina

**Study participating centre****Hospital Alemán**

Av. Pueyrredón 1640

Ciudad Autónoma de Buenos Aires

Argentina

1118

## **Sponsor information**

**Organisation**

Takeda Pharmaceutical Company Limited

**Sponsor details**

One Takeda Parkway

Deerfield, IL

United States of America

60015

**Sponsor type**

Industry

**ROR**

<https://ror.org/03bygaq51>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Takeda Pharmaceuticals U.S.A.

**Alternative Name(s)**

Takeda, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals America, Inc., Takeda in the U.S., TPUSA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in gastroenterology journals and disseminate the study results on the six months after ended the study.

**Intention to publish date**

30/11/2018

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Other