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

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| **Submission date** | **Recruitment status** | [X] Prospectively registered |
| 21/07/2016 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 17/08/2016 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 15/08/2016 | Digestive System | [ ] 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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# Additional identifiers

### Protocol serial number
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 laringoscopic 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

## Study type(s)
Other

## 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(s)
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.

## Key secondary outcome(s))
No seconday outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
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# Sponsor information

**Organisation**
Takeda Pharmaceutical Company Limited

**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., Takeda in the United States, Takeda U.S., Takeda Pharmaceuticals North America, Inc., TPUSA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

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

**IPD sharing plan summary**

Other