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Predictors of symptomatic response to pantoprazole in patients with laryngopharyngeal reflux

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

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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
Ciudad Autónoma de Buenos Aires
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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