

# Diagnosis of Laryngopharyngeal Reflux (LPR) in patients with Hoarseness and Globus: is aerosolized oropharyngeal pH monitoring adequate?

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Primary objective: to objectively diagnose LPR in patients with hoarseness and/or globus complaints, and a Reflux Symptom Index (RSI) > 13. Secondary objective: To assess the accuracy of the Restech Dx-pH probe™ compared to the dual 24h pH probe

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32450

### Source

ToetsingOnline

### Brief title

Laryngopharyngeal Reflux and Oropharyngeal pH measurements

### Condition

- Other condition
- Oral soft tissue conditions

### Synonym

Extraesophageal reflux, heartburn

### Health condition

Laryngopharyngeal Reflux (LPR)

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Sint Lucas Andreas Ziekenhuis

**Source(s) of monetary or material Support:** Het onderzoek valt binnen het kostendeel van de gedeclareerde DBC's.

## Intervention

**Keyword:** Hoarseness, LPR, Oropharynx, pH

## Outcome measures

### Primary outcome

During 24 hours:

- mean pH
- percentage of time with pH <4.0/4.5/5.0/5.5/6.0/6.5
- number of pH events <4.0/4.5/5.0/5.5/6.0/6.5.

### Secondary outcome

Not applicable.

## Study description

### Background summary

Laryngopharyngeal Reflux (LPR) is the retrograde movement of gastric contents into the laryngopharynx, which can cause complaints of hoarseness and globus. Dual probe pH measuring and test treatment with Proton Pump Inhibitors (PPI\*S) have been used as diagnostic tools, however, an objective diagnostic procedure is missing. Recent studies have described the Restech Dx-pH probe<sup>TM</sup>, a minimally invasive oropharyngeal pH measurement probe, as an adequate tool to measure the pH

### Study objective

Primary objective: to objectively diagnose LPR in patients with hoarseness

and/or globus complaints, and a Reflux Symptom Index (RSI) > 13. Secondary objective: To assess the accuracy of the Restech Dx-pH probe™ compared to the dual 24h pH probe

## Study design

Prospective observational study.

## Study burden and risks

Subjects will pay two visits to the hospital: the first for placement of the probes, the second for removing them. There are minor risks of nose bleeding, nausea, discomfort in throat and irritation from xylocaine spray and sticky tape. Two questionnaires have to be filled in, which will take 20 minutes. Patients with hoarseness and globus with an RSI>13 but without the diagnosis of LPR are interesting study subjects for determining the pH in the oropharynx.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

## Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- Patients with hoarseness and/or globus, RSI>13 (n<=20)
- Patients without hoarseness and globus, RSI>13 (n<=20)
- Subjects without hoarseness and globus, RSI<13 (n<=20)

## Exclusion criteria

anatomical abnormalities that can explain hoarseness (eg polyp), functional abnormalities that can explain hoarseness (speech therapy related), malignancies, usages of PPI\*s or H2 antagonists, pregnancy or lactating, smoking

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO

Date: 11-11-2009

Application type: First submission

Review commission: METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL29923.029.09