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 asses the accuracy of the Restech Dx-pH probeTM compared to the dual 24h pH probe

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	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

Laryngofaryngeale Reflux (LFR)

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 probeTM, 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 asses the accuracy of the Restech Dx-pH probeTM 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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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with haorseness 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