Comparative Effectiveness of Alginate, Magaldrate, Sucralfate, Proton Pump Inhibitors, and Diet in Laryngopharyngeal Reflux Disease : A Randomized Controlled Trial

NCT number :

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Study objectives :

Proton pump inhibitors (PPIs) are commonly prescribed for the management of laryngopharyngeal reflux disease (LPRD); however, their efficacy remains controversial. Several studies have failed to demonstrate a significant benefit of PPIs over placebo in this condition.

Furthermore, long-term PPI use has been associated with potential adverse effects, including an increased risk of gastrointestinal infections, rebound acid hypersecretion following treatment discontinuation, impaired absorption of micronutrients (eg: vitamin B12 deficiency and hypomagnesemia), as well as possible associations with renal dysfunction and cognitive decline in elderly populations.

Alternative therapeutic approaches targeting gastroduodenal and gastro-esophago-pharyngeal reflux are available but remain underutilized.

The aim of this study is to evaluate the effectiveness of alternative pharmacological treatments and an anti-acid diet compared to PPIs in the management of LPRD.

Materiels and Methods :

The physician performs a physical examination and completes the Reflux Sign Assessment (RSA) score. This scoring system is divided into three sections according to the location of the findings: the oral cavity, pharynx, and larynx. The overall score is obtained by summing the individual item scores, with a maximum possible total of 61. The RSA is used both for the diagnosis and for monitoring patients with suspected LPRD, as well as those whose diagnosis has been confirmed by pH studies.
Finally, an additional form (Reflux Symptom Score- RSS) will assess ENT, digestive, respiratory, and behavioral symptoms using severity, frequency, and impact scales. The values correspond to the following criteria:

Frequency:

- 0 = absence of symptoms
- 1 = 1–2 times per week
- 2 = 2–3 times per week
- 3 = 3–4 times per week
- 4 = 4–5 times per week
- 5 = daily or several times per day

Severity:

- 0 = not bothersome
- 5 = very bothersome when present

Impact:

- 0 = no impact on the child’s quality of life

- 5 = major impact

These questionnaires must be completed in full.

Participants

a) Inclusion criteria:

-Positive 24-h HEMII-pH > 1 event

b) Exclusion criteria:

- Smoker (>5 cigarettes/day) , alcohol dependence (>3 units/day),
- upper respiratory tract infection within the last month,
- pregnancy,
- neurological or psychiatric illness,
- previous history of neck surgery or trauma,
- malignancy,
- history of head and neck radiotherapy
- active seasonal allergies or asthma.

Statistical Analysis

The collected data will be entered into an Excel database for statistical analysis. Descriptive statistics will be used to summarize patient characteristics and score distributions.

Paired analyses will be performed. If the data are normally distributed, a paired *t*-test will be used. If normality assumptions are not met, the Wilcoxon signed-rank test will be applied.

Normality will be assessed using the Shapiro–Wilk test and graphical methods. Results will be expressed as mean ± standard deviation or median with interquartile range, as appropriate.

A p-value < 0.05 will be considered statistically significant.

Clinical Follow-up

Patients will be assessed at baseline (month 0, prior to treatment initiation) and at 3 months post-treatment to evaluate treatment response using the RSS and RSA scores.