

LEFTSTYLE advice for nocturnal reflux symptoms

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29495

Source

NTR

Brief title

LEFTSTYLE

Health condition

Reflux disease

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Treatment success, defined as a 50% reduction in Nocturnal GERD Symptom Severity score from baseline (N-GSSIQ questionnaire).

Secondary outcome

- Nocturnal reflux free nights (measured by symptom diary on daily basis – one question)
- Change in reflux symptoms (measured by RDQ & symptom diary)
- Change in nocturnal reflux symptoms (measured by N-GSSIQ questionnaire and symptom diary)
- Change in work productivity (measured by WPAI-GERD questionnaire).
- Change in sleep position during study (supine, prone, left lateral decubitus or right lateral decubitus).
- Change in sleep quality (measured by the PSQI questionnaire)
- Global assessment of treatment on nocturnal reflux symptoms (“ Compared to the start of the treatment, how would you rate your nocturnal reflux symptoms now?”)

Study description

Background summary

Gastroesophageal reflux disease (GERD) is one of the most common gastro-intestinal disorders with an estimated prevalence of 7%-33% worldwide and results in a major burden on the health care system given medical visits, costs of treatments and loss of work productivity (1). Treatment of GERD in general consists of lifestyle changes, acid-suppressive medication and sometimes surgery, depending on the severity of the disease. However, a large proportion of patients with reflux disease remain under treatment at the general practitioner or help themselves in which lifestyle advice and over the counter obtained acid suppressive medication.

Approximately 50-80% of the GERD patients experience symptoms at night; known as nocturnal reflux disease (2). Nocturnal reflux disease has a negative impact on sleep quality and daytime functioning. It has been shown that body position during profound sleeping has an effect on nocturnal gastroesophageal reflux. When sleeping in a left lateral decubitus position, the stomach is positioned below the esophagus, resulting in less reflux episodes. Recently, we started the LEFT study (NL71355.018.019) where we investigate the effect of LEFT (an electronic sleep position training device) for the treatment of nocturnal reflux symptoms in tertiary care patients, the first results are very encouraging. However, that first study does not contain a control or sham treatment arm. The LEFT is a small, lightweight, non-invasive and affordable anti-reflux device. The device is placed, with a double sided self-adhesive tape, on the chest of the patients. The LEFT will gently vibrate when the body is in a right side position. Preliminary results we have shown that within a couple of days, patients and healthy volunteers do not sleep on their right side anymore.

Positional therapy may thus provide a simple, cheap and effective treatment of nocturnal reflux symptoms. In addition to the severe GERD patients in which we are performing the first study with LEFT, we think this device is could be very effective for people with moderate nocturnal reflux complaints in the primary and self-care setting as well.

1. El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut*. 2014;63(6):871-80.
2. Shaker R, Castell DO, Schoenfeld PS, Spechler SJ. Nighttime heartburn is an under-

appreciated clinical problem that impacts sleep and daytime function: the results of a Gallup survey conducted on behalf of the American Gastroenterological Association. The American journal of gastroenterology. 2003;98(7):1487-93.

Study objective

The main objective of the study is to investigate if positional therapy during sleeping, using the LEFT device, reduces nighttime gastroesophageal reflux symptoms.

Study design

Baseline, After 2 weeks and after 3 weeks.

Intervention

The LEFT is a wearable device attached to the upper chest before patients go to bed using double sided self-adhesive tape and helps patients with nocturnal reflux complaints to sleep more on their left side. The LEFT will gently vibrate when the body is in the “wrong” sleep position (right side position) so it conditions people to roll over to the left side. The sham group will consist of an identical device but programmed with different software that does not vibrate; patient will only receive sleep advice (sleep on your left side). The sham group will only vibrate in the first 30 minutes of the night.

Contacts

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Eligibility criteria

Inclusion criteria

-Written informed consent.

- Both male and female patients will be included.
- Age above 18 years.
- Symptoms of heartburn and/or acid regurgitation at least 3 times a week during the night.
- A total reflux symptom score ≥ 8 (measured through the GERDQ questionnaire score).

Exclusion criteria

- Nightshift workers
- Surgery of the esophagus or stomach.
- Regular use of sleep medication (benzodiazepines) that cannot be stopped during the duration of the trial.
- Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders).
- Patients with obstructive sleep apnea.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2020
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 25-05-2020

Application type: First submission

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
NTR-new	NL8655
Other	METC AMC : METC2020_058

Study results