

# LEFTSTYLE advice for nocturnal reflux symptoms

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal motility and defaecation conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49851

### Source

ToetsingOnline

### Brief title

LEFTSTYLE

## Condition

- Gastrointestinal motility and defaecation conditions

### Synonym

gastroesophageal reflux disease

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** gastroesophageal, positional, reflux, therapy

## Outcome measures

### Primary outcome

Treatment success: defined as a 50% reduction in Nocturnal GERD Symptom Severity score from baseline (N-GSSIQ). We considered a 50% reduction in severity score as clinically significant.

### 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).
- 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. 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 GP or help themselves with self-care advice in which lifestyle advice and acid suppression are the cornerstone of the treatment.

It has been shown that body position during sleeping has an effect on nocturnal gastroesophageal reflux. A technique to reduce gastroesophageal reflux is to use gravity to prevent the acidic gastric content going up into the esophagus. Sleeping with an extra pillow or raising the head-end of the bed is a simple technique often advised to patients to reduce nocturnal reflux episodes. Furthermore, it is well established that sleeping in a left lateral decubitus position reduces reflux occurrence during nighttime. When sleeping in a left lateral decubitus position, the stomach is positioned below the esophagus, resulting in less reflux episodes. Electronic sleep position training devices have already been proven in patients with sleep apnea and excessive snoring, in which patients are trained by means of vibration to turn from the back to the left or right side. By adapting this device's vibration/position threshold, it is also possible to train patients to lie on their left side, thereby reducing nocturnal reflux. Positional therapy may thus provide a simple, cheap and effective in the treatment of GERD.

We have recently started a similar study, called LEFT, known to you under number NL71355.18.19. A large proportion of the patients who experience nocturnal reflux complaints will look on the internet for advice, buy over the counter acid suppressive medication or will visit the general practitioner for advice. We hypothesize the LEFT device is well-suited for these patients with moderate reflux symptoms.

## **Study objective**

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

## **Study design**

A single center, prospective, randomized, double blind, sham-controlled trial.

## **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 (only the first 20-30 minutes); patient will only receive sleep advice (sleep on your left side).

## **Study burden and risks**

Electronic sleep position training devices have already been proven in patients with sleep apnea and excessive snoring, in which patients are trained by means of vibration to turn from the back to the left or right side. This opens up the airway resulting in a significant reduction in snoring and sleep apnea episodes. The LEFT is adapted version from the SNOOOR; a small, lightweight, non-invasive and affordable anti-snoring wearable device.

The SNOOOR is used for positional therapy in patients who only snore when they sleep on their back (supine). The device is placed, with a self-adhesive sticker, on the forehead or the chest of the patient. It trains patients to sleep on their side or their head tilted sideways, opening the airway and reducing or eliminating the snoring. Similar electronic position trainers have been proven effective in reducing sleep apnea episodes and snoring. Increasing evidence has showed that active positional therapy may play a role in the treatment of nocturnal gastroesophageal reflux. A simple modification to the device, now known as LEFT, has changed it into a possible anti-reflux device. Given that GERD is considered a disease while snoring is not, the LEFT is a medical device while the SNOOOR is not.

The burden of participating patients will be one hospital visit and filling out questionnaires about reflux symptoms (not psychologically stressful). For patients randomized to LEFT, sleep quality may be disturbed in the first nights due to the vibrations when they turn towards the \*wrong\* position in their sleep. However, after a couple of nights, patients will sleep more and more in the correct position (left side) and there will be hardly any vibrations anymore.

In conclusion, positional therapy using LEFT may thus provide a simple, cheap and effective in the treatment of nocturnal gastroesophageal reflux symptoms. There are no potential issues of concern.

## **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

- 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  $\geq 8$  (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 phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2020
Enrollment:	100
Type:	Actual

### Medical products/devices used

Generic name:	LEFT (electronic sleep position training device)
Registration:	No

## Ethics review

Approved WMO	
Date:	06-04-2020
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	NL72948.018.20