Sleep positional therapy for the treatment of nocturnal gastroesophageal reflux

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21478

Source
NTR

Brief title
LEFT

Health condition

Reflux disease

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Manufacturer of the device

Intervention

Outcome measures

Primary outcome

Change in total nocturnal acid exposure time during pH-impedance studies

Secondary outcome

-Change in number of nocturnal gastroesophageal reflux episodes (both mixed/liquid reflux episodes and both acidic and non-acidic episodes)
-Esophageal acid clearance time.
-Sleep position during study (supine, prone, left lateral decubitus or right lateral decubitus).
-Relation between sleep positions and reflux parameters.
-Frequency of reflux symptoms during the night (measured by symptom diary and pH-measurement).
-Questionnaires:
o GERDQ questionnaire
o Reflux Disease Questionnaire (RDQ) score
o The Pittsburgh Sleep Quality Index (PSQI)
o Nocturnal Gastroesophageal Reflux Disease (GERD) Symptom Severity and Impact Questionnaire (N-GSSIQ).
o Global assessment of treatment success.

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 acid suppressive medication.
It has been shown that body position during 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. The efficacy of 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 (2, 3). By adapting the vibration/position threshold of such a device, 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.

Study objective

The main objective of the study is to assess the effect of sleep positional therapy, using the LEFT device, on nocturnal gastroesophageal reflux.

Study design

Baseline and after 2 weeks of treatment.

Intervention

The LEFT is a wearable device worn on the upper chest 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).

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 2 times a week during the night.
-A total reflux symptom score ≥8 (measured through the GERDQ questionnaire score).
-Minimal of 1.5% esophageal acid exposure during the night.

Exclusion criteria

-Surgery of the GI tract other than appendectomy or cholecystectomy.
-Use of any medication with a potential effect on gastrointestinal motility, secretion or sensitivity that cannot be stopped for the duration of the study (e.g. H2-blockers, antidepressants, prokinetics).
-History of gastrointestinal cancer.
-Known diabetes.
-Regular use of sleep medication (benzodiazepines) that cannot be stopped.
-Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung

disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders).
-Pregnant or lactating women. Women will be asked if they are pregnant.
-Patients that sleep >75% of Total Sleep Time (TST) on their left side
-Patients that sleep <10% of TST on their right side

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-12-2019
Enrollment:	45
Type:	Anticipated

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	NL8657
Other	METC AMC : METC2020_220

Study results