Sleep positional therapy for the treatment of nocturnal gastroesophageal reflux

Gepubliceerd: 25-05-2020 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21478

Bron
NTR

Verkorte titel
LEFT

Aandoening

Reflux disease

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Manufacturer of the device

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Baseline and after 2 weeks of treatment.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Amsterdam UMC (locatie AMC)
Jeroen M. Schuitenmaker

+31205662199

Wetenschappelijk

Amsterdam UMC (locatie AMC)
Jeroen M. Schuitenmaker

+31205662199

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-12-2019
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8657
Ander register	METC AMC : METC2020_220

Resultaten