

Electrical contrastimulation on the calf for Restless Legs

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LEXO reduces symptoms of Restless Legs.

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

Samenvatting

ID

NL-OMON27456

Bron

NTR

Verkorte titel

LEXO

Aandoening

Restless Legs Syndrome

Ondersteuning

Primaire sponsor: Relegs

Overige ondersteuning: Relegs

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Visual Analog Scale on RLS symptoms (VAS).

Toelichting onderzoek

Achtergrond van het onderzoek

Restless Legs Syndrome (RLS) is a sensorimotor disorder characterized by an irresistible urge to move the legs to stop unpleasant sensations. These unpleasant sensations are usually experienced in the calves and range in severity from discomfort to painful. The exact cause of RLS remains unknown and there is no cure. Treatment is directed at symptom relief only, which can be achieved with pharmaceuticals or conservatively. Existing pharmacotherapy can only be administered to target specific patients, is not practical in every RLS triggering situation, and is not very popular due to the related adverse effects. Transcutaneous electrical nerve stimulation (TENS) is a safe non-pharmacological treatment modality for a variety of pain conditions and it has been shown that TENS can reduce symptoms of RLS. Therefore, to treat RLS with TENS could offer additional efficacy and improve the therapeutic repertoire for RLS, with fewer side effects. LEX0 is a novel TENS device designed to place on the calf, specifically for the treatment of RLS.

Doel van het onderzoek

LEX0 reduces symptoms of Restless Legs.

Onderzoeksopzet

Before and after each treatment with LEX0: VAS
Visit 1 (begin study) : IRLS, MOS-sleep, RLS-QoL
Visit 2 (end study) : IRLS, MOS-sleep, RLS-QoL

Onderzoeksproduct en/of interventie

Subjects are instructed to use LEX0 for 4 weeks in home environment for their restless legs, as needed. An user manual is handed. In the event of an RLS attack, LEX0 is placed with the electrode patch on the skin of the calf and the preset treatment program of 30 minutes is started. There are three levels of intensity and the most comfortable intensity level below painful threshold must be chosen. Subjects can stop treatment any time. In case of a prolonged attack treatment can be continued. Before and after each treatment session a VAS on RLS symptoms is scored. During the four-week study subjects keep a diary. Subjects have to visit the clinic at the begin and end of the study, and fill in questionnaires related to RLS and LEX0 usability.

Contactpersonen

Publiek

Centrum Oosterwal
casper van waveren Hogervorst

0619626021

Wetenschappelijk

Centrum Oosterwal
casper van waveren Hogervorst

0619626021

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- age >18 < 80 yrs;
- 5 essential diagnostic criteria RLS according IRLSSG;
- RLS attack $\geq$ once a week.

IRLSSG: International Restless Legs Syndrome Study Group

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- RLS medication
- Cardiac pacemaker, Implanted defibrillator, Transdermal drug delivery system
- Open wounds, skin eruptions or infected areas on legs
- Lack of normal sensation in legs
- Deep vein thrombosis during last 6 months
- Another sleep disorder
- Another movement disorder (e.g. Parkinson disease, dyskinesia, or dystonia)
- Epilepsy
- Pregnancy

Onderzoekopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	02-10-2019
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	09-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48228
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7672
CCMO	NL68957.098.19
OMON	NL-OMON48228

Resultaten

Samenvatting resultaten

N/A