Electrical contrastimulation on the calf for Restless Legs

Published: 22-08-2019
Last updated: 15-05-2024

To assess the efficacy of LEX0 on the calf for Restless Legs (RLS)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON48228

Source
ToetsingOnline

Brief title
LEX0 Study

Condition

- Sleep disturbances (incl subtypes)

Synonym
Restless Legs Syndrome (RLS), Willis Ekbom disease

Research involving
Human

Sponsors and support

Primary sponsor: Relegs
Source(s) of monetary or material Support: Relegs BV

Intervention

Keyword: Contrastimulation, Restless Legs, RLS, TENS

Outcome measures

Primary outcome

Difference in VAS score before and after the use of LEX0 during an RLS attack.

Secondary outcome

- Difference in MOS-sleep before and after 4 weeks of LEX0 use in home environment.

- Difference in RLS-QoL score before and after 4 weeks of LEX0 use in home environment.

- Difference in IRLS score before and after 4 weeks of LEX0 use in home environment.

- Registering adverse reactions and serious adverse events.

Study description

Background summary

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.

Hypothesis: LEX0 reduces symptoms of Restless Legs (RLS).

Study objective

To assess the efficacy of LEX0 on the calf for Restless Legs (RLS)

Study design

Prospective interventional studyl

Intervention

Subjects are instructed to use LEX0 for 4 weeks in home environment. A 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. The most affected leg must be treated. There are three levels of intensity and the most comfortable intensity level below the pain threshold is chosen. LEX0 does not have to be used with every RLS attack and in case of a prolonged attack treatment can be continued. Treatment can be stopped at any time. Before and after each treatment a VAS on RLS symptoms is scored. During the four-week study subjects keep a diary. Subjects visit the clinic twice, both times 3 short validated questionnaires about RLS are completed (IRLS, MOS sleep, RLS-QoL). During the last visit also a questionnaire about LEX0 usability is taken.

Study burden and risks

Subject has to visit the clinic two times; at the beginning and end of the study. During these visits subject completes 3 questionnaires related to RLS. At the end of the study also a questionnaire about LEX0 usability is taken. The study duration is 4 weeks in home environment. Subject uses LEX0 as needed and measures leg discomfort by scoring VAS, before and after treatment. Throughout the study, subject keeps a diary. There are no risks associated with the investigational treatment; TENS is an established safe non-pharmacological treatment modality to use at home for many different pain conditions. There are no good treatment options for RLS and farmacotherapy has its limitations. Subject may benefit from this treatment with experiencing symptom relief. By exception subject may experience a mild skin reaction beneath the stimulation electrode applied or (muscle)pain or cramps in the calf.

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

* Age >18 < 80 yrs;
* 5 essential diagnostic criteria RLS according to IRLSSG;
* RLS attack * once a week.IRLSSG <= International Restless Legs Syndrome Study Groupormuli

Exclusion criteria

* RLS medication
* Cardiac pacemaker, Implanted defibrillator, Transdermal drug delivery system
* Open wounds, skin eruptions or infected areas on legs/calves
* Lack of normal sensation in legs/calves

* Deep vein thrombosis during last 6 months
* Another sleep disorder
* Another movement disorder (e.g. Parkinson disease, dyskinesia, or dystonia)
* Epilepsy
* Pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2019
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Transcutaneous Electrical Nerve Stimulation (TENS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27456
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68957.098.19
Other	NL7672
OMON	NL-OMON27456