Electrical contrastimulation on the calf for Restless Legs

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27456

Source
Nationaal Trial Register

Brief title
LEX0

Health condition

Restless Legs Syndrome

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Visual Analog Scale on RLS symptoms (VAS).

Secondary outcome

RLS severity (IRLS), Sleep (MOS-sleep), Quality of Life (RLS-QoL) and Safety (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.

Study objective

LEX0 reduces symptoms of Restless Legs.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

IRLSSG: International Restless Legs Syndrome Study Group

Exclusion criteria

- 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

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

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	09-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48228
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A