The effect of the STIL brace on forearm tremor - a double-blind randomized crossover study

Published: 07-10-2019
Last updated: 09-04-2024

Primary objective: - To evaluate the effect of the STIL brace on tremor amplitude in patients with forearm tremor. Secondary objectives: - To evaluate the effect of the STIL brace on patients* impressions of tremor severity.- To assess patient...

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON48254

Source
ToetsingOnline

Brief title
Suppression of the forearm tremor with the STIL brace

Condition

- Movement disorders (incl parkinsonism)

Synonym
invalidating forearm tremor, shaky hands

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Geen;het Reinier de Graaf ontvangt geen vergoeding voor het onderzoek. De brace wordt in bruikleen gegeven en zal enkel voor

onderzoeksdoeleinden worden gebruikt.

Intervention

Keyword: Active device, Brace, Suppression, Tremor

Outcome measures

Primary outcome

The primary outcome of this study is tremor amplitude, measured with accelerometry sensors with gyro on the hand and the arm. The tremor amplitude will be compared over the three situations (without brace, with active brace and with passive brace). We expect a tremor amplitude reduction of at least 50% with brace suppression compared to the situation without brace.

Secondary outcome

Secondary outcomes are:

- Subjective severity of the tremor, measured with the Patient Global Impression of Severity (PGI-S)

- Patient satisfaction with regards to the brace, measured with the Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST) and an extra questionnaire developed by STIL to get more specific feedback on the brace.

Study description

Background summary

Tremor is the most common movement disorder. Forearm tremor affects fine fine motor control and can therefore have a big functional impact, impairing daily activities such as writing, drinking, or dressing. Current treatment (medication and brain surgery) often do not have the desired effect and

side-effects are known. Nowadays, devices are known that target the symptoms instead of the origin of the disorder. These devices make use of mechanical suppression or muscle/nerve stimulation in order to reduce the tremor severity. However, these devices are often task specific, bulky and awkward to wear and restricting voluntary movement.
Therefore, the STIL brace is developed; a wrist brace that is easy to wear and suppresses the tremor by producing an anti-vibration, without restricting voluntary movements.This brace will be tested on patients to evaluate the effect of the brace on tremor severity and to assess patient satisfaction. The hypothesis is that the brace will suppress the tremor which will lead to a tremor amplitude reduction of at least 50%.

Study objective

Primary objective:
- To evaluate the effect of the STIL brace on tremor amplitude in patients with forearm tremor.

Secondary objectives:
- To evaluate the effect of the STIL brace on patients* impressions of tremor severity.
- To assess patient satisfaction with regards to the usability and comfort of the STIL brace.

Study design

Randomized double-blind crossover study.
Tremor severity will be measured in 3 situations: without brace (baseline), with brace in active mode (intervention) and with brace in passive mode (placebo). The order of the modes in which the brace functions, will be randomly assigned by the computer. In passive mode, the brace sounds and looks looks the same as in the active mode, but no vibrations are produced. In this way the investigator nor the patient knows when the brace is on or off.

Intervention

The intervention is the STIL brace that suppresses the tremor in the active mode. In this condition, different movements and postures are performed with the hand/arm during which the tremor amplitude will be registered. This takes about 10 minutes.

The placebo condition is when the STIL brace functions in passive mode. The same procedure will be repeated as with the active brace while the tremor amplitude is measured. The passive mode will be assessed to evaluate the effect of the weight of the brace on tremor amplitude.

The order of the modes will be randomly assigned by a computer.

Study burden and risks

Based on the risk analysis that is performed, it can be expected that there are minimal risks for the participants. The brace will be worn for a maximum of 30 minutes, the brace will only interact with the intact skin, patients are not at high risk and precautionary measures are taken. In case the brace functions not as expected, despite the safety measures, it can be detached directly.

Contacts

Public
Reinier de Graaf Groep

Reinier de graafweg 5
Delft 2625 AD
NL
Scientific
Reinier de Graaf Groep

Reinier de graafweg 5
Delft 2625 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients over 18 years old
* Competent and willing to sign informed consent
* Significant disability due to forearm tremor. (ADL score of 3 or above in one of the upper limb items and a minimum subset score of 38 across all upper limb items. Scored for the most affected hand with the Bain and Findley ADL scale)

Exclusion criteria

* Excessive alcohol consumption, as defined in the GGZ guidelines
* Implanted electrical medical device, such as a pacemaker, defibrillator, or deep brain stimulator
* Previous thalamotomy procedure, including stereotactic thalamotomy, gamma knife radio surgical thalamotomy, and focused ultrasound for the treatment of tremor
* Change in medication in the 30 days prior to study enrollment
* Taking medication known to exacerbate tremor
* Suspected or diagnosed epilepsy
* Swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions of skin at stimulation site.
* Peripheral neuropathy affecting the tested upper extremity (e.g. Carpal tunnel syndrome)
* Presence of any other neurodegenerative diseases like multisystem atrophy, progressive supranuclear palsy, dementia with Lewy bodies, and Alzheimer's disease.
* Patients diagnosed with a depression
* Patients with an amputation of one or both upper extremities.
* Subjects with a restricted movement of the arm and or hand (e.g. contractures) or restricted muscle function
* Botulinum toxin injection for hand tremor within 6 months prior to study enrollment
* Alcohol or caffeine consumption within 24 hours of study enrollment.
* Heavy physical training within 24 hours of study enrollment
* Subjects unable to communicate with the investigator and staff
* Subjects with illiteracy
* Pregnancy at time of study enrollment

Study design

Design

Study phase: 2

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	STIL brace
Registration:	No

Ethics review

Approved WMO

Date:	07-10-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL69132.098.19