The effect of the STIL anti-tremor orthosis on reduction of forearm tremor in Essential Tremor patients - a single blind randomized crossover study

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The primary aim of this research is:- To investigate the effect of the STIL orthosis on the tremor severity and amplitude in patients with forearm tremor.Secondary goals of this research are:- Assess patient satisfaction with orthosis efficacy and…

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

Summary

ID

NL-OMON51742

Source
ToetsingOnline

Brief title
Suppression of forearm tremor with the STIL anti-tremor orthosis

Condition

- Movement disorders (incl parkinsonism)

Synonym
invalidating arm tremor, trembling 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 orthese wordt in bruikleen gegeven en zal enkel voor onderzoeksdoeleinden worden gebruikt.

Intervention

Keyword: Orthosis, Passive medical device, Suppression, Tremor

Outcome measures

Primary outcome

Quantification of tremor severity will be based on the TETRAS scale, from which 7 tasks (postural out-stretched arms, postural wingbeat, finger-to-nose, eating, drinking, pouring, writing) are selected that justly represent the obstruction that ET patients experience in daily life.

A TETRAS score is rated on the baseline, sham and intervention conditions. Combining the 7 tasks from the TETRAS scale, a maximum scoring of 28 points can be achieved per condition. The expectation is that orthosis will reduce TETRAS score by at least on categorial measure (e.g. from severe to moderate).

Quantification of tremor amplitude will be based on movement data from an Inertial Measurement Unit (IMU). Again the same 7 tasks (postural out-stretched arms, postural wingbeat, finger-to-nose, eating, drinking, pouring, writing) are used to compare baseline, sham and intervention conditions.

A measure for overall tremor amplitude is calculated per test subject, for every selected TETRAS task. The expectation is that the orthosis reduces tremor amplitude by 60% between baseline and intervention.

See Chapter 7 of the Clinical Investigation Plan for more information.

Secondary outcome

The secondary outcome measure, patient satisfaction, will be scored to test patient satisfaction with respect to comfort and usability of the orthosis with the Dutch Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST).

This questionnaire consists of 8 questions about the device itself and 5 questions about the manufacturer's service. Only the part about the device itself will be questioned.

Satisfaction is measured on a scale of 1-5, ranging from 'not at all satisfied' to 'very satisfied'. Additional questions, posed by STIL, will be asked to further investigate comfort and usability.

The other secondary outcome measure is intended to list the adverse events reported by the patients themselves (from D-QUEST) and from the adverse event forms that the investigator will fill out. This will provide a basis from which safety of the device can be deduced.

Health related quality of life will be assessed at the intervention, in order to correlate this to the effect on patient satisfaction.

See Chapter 7 of the Clinical Investigation Plan for more information.

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 STIL anti-tremor orthosis is developed; a wearable medical device that suppresses the tremor by adding artificial (passive) damping to the joints in the forearm. This orthosis will be tested on patients to investigate the effectiveness and comfort of the device. It is hypothesized that orthosis reduces tremor by more than 60%.

Study objective

The primary aim of this research is:
- To investigate the effect of the STIL orthosis on the tremor severity and amplitude in patients with forearm tremor.

Secondary goals of this research are:
- Assess patient satisfaction with orthosis efficacy and comfort

Health related quality of life will also be assessed.

See Chapter 2 of the Clinical Investigation Plan for more information.

Study design

Single blind randomized crossover study, comparing a baseline with an interventional orthosis and a sham orthosis.

See Chapter 3 of the Clinical Investigation Plan for more information.

Intervention

The STIL anti-tremor orthosis suppresses the tremor in the forearm. The sham orthosis will only have weight effects.

See Chapter 7 of the Clinical Investigation Plan for more information.

Study burden and risks

The patients will wear the passive, non-invasive orthosis for a maximum of 60 minutes at a time.

Based on the Benefit-Risk analysis, the risks associated with this research are estimated to be small, but the (indirect) benefits for this patient group are very high when the product is available.

See IMDD, Appendix 5 for more information.

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

- Diagnosed with Essential Tremor
- Significant disability due to forearm tremor, retrieved from Bain and Findley ADL score (>30)
- Tremor severity score >13 on subset of TETRAS scale
- Dominant wrist flexion/extension and forearm pronation/supination tremor
- > 18 years old

Exclusion criteria

• Dominant shoulder internal/external rotation tremor
• Dominant elbow flexion/extension tremor
• Excessive alcohol consumption, as defined in the GGZ guidelines on alcohol use 21
• Previous or planned Deep Brain Stimulation (DBS) at time of study enrollment that interferes with testing.
• Previous or planned thalamotomy procedure, including stereotactic thalamotomy, gamma knife radio surgical thalamotomy, and focused ultrasound for the treatment of tremor at time of study enrollment that interferes with testing.
• Change in medications related to tremor disorder in the 30 days prior to study enrollment
• Swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions of skin on the forearm or hand that would interfere with wearing the orthosis during the clinical investigation.
• Peripheral neuropathy affecting the tested upper extremity (e.g. Carpal tunnel syndrome)
• The suspicion or confirmation that head tremor may cause impairment in performing ADL tasks
• Diagnosed Parkinson*s disease, this includes presence of parkinsonian features
• Diagnosed functional tremor
• Diagnosed physiologic tremor
• Diagnosed cerebellar tremor
• Diagnosed Multiple Sclerosis (MS)
• Diagnosed ataxia
• Patients with an amputation of one or both upper extremities.
• Subjects with a restricted movement or restricted muscle function in the arm and or hand (e.g. contractures)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2022
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	STIL anti-tremor orthosis
Registration:	No

Ethics review

Approved WMO

Date:	21-12-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	01-08-2022
Application type:	Amendment
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	NL79108.000.21