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Reduction of tremor in essential tremor patients by use of a new anti-tremor device

Submission date
03/05/2023

Recruitment status
No longer recruiting

Registration date
30/05/2023

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Essential tremor is the most common neurological movement disorder. Tremor in the arms affects fine motor control and can lead to impairment in activities of daily living, such as writing, drinking or writing. Current treatments to suppress essential tremors, such as medication (e.g., propranolol, primidon) and deep brain stimulation, often do not have the desired effectiveness and/or have side effects and risks. In this study, a new anti-tremor orthosis (device) that aims to reduce tremors by adding artificial (passive) damping to the joints in the forearm, is evaluated for its effectiveness, patient satisfaction and adverse events.

Who can participate?
Patients aged over 18 years with essential tremor

What does the study involve?
Participants perform seven standardized tasks in three conditions: baseline (wearing no devices), wearing a sham device, and wearing the new anti-tremor orthosis. They are randomly assigned to either the sham device first or the orthosis first and do not know which device was the sham or the orthosis, but the investigator will know.

What are the possible benefit and risks of participating?
The benefit of participating is contributing to research that could potentially lead to a new treatment option for essential tremor patients. Risks are deemed minor: the interventional devices are non-invasive, do not use nerve- or muscle stimulation, and participants wear the devices for a short period in a controlled clinical setting. Expected side effects are redness of the skin or hand discomfort. Apart from travel cost reimbursement, participants receive no reimbursement.

Where is the study run from?
The Reinier de Graaff Hospital (The Netherlands)

When is the study starting and how long is it expected to run for? -
August 2021 to October 2022.

Who is funding the study?
The Reinier de Graaff Hospital (The Netherlands)

Who is the main contact?
Daan Kamphuis, kamphuis@rdgg.nl

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL79108.000.21

Study information

Scientific Title
The effect of a novel anti-tremor orthosis on reduction of forearm tremor in essential tremor patients - a single-blind randomized crossover study

Study objectives
A novel anti-tremor orthosis reduces tremor severity and tremor amplitude in essential tremor patients with a dominant forearm tremor, in comparison with baseline (no orthosis) or a sham device.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 21/12/2021, amended 01/08/2022, the Dutch medical-ethical committee of Leiden-Delft-Den Haag (METC LDD, Kamer P5-22, Route 953, Postzone P5-P, Postbus 9600, 2300 RC Leiden, the Netherlands; +31 (0)71 526 5106; n.feller@lumc.nl), ref: NL79108.000.21

Study design
Single-center single-blind randomized crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reduction of tremor in patients with essential tremor with a dominant forearm tremor.

Interventions
An algorithm within the CRF software, which includes the API that is used to acquire the motion data, will randomly determine the order of the sham device and intervention. Only the investigator can see which device is selected, thereby blinding the patient. The investigator will obtain the selected device using colour-coded tabs and attach it to the patient's arm/hand. Both devices will have a comparable look and weight.

The study compared participants in three conditions: baseline (no orthosis), wearing a sham device; and wearing the novel anti-tremor orthosis. The sham device, albeit identical in weight and appearance to the orthosis, contained no damping elements designed for tremor suppression and did not restrain movement of the forearm.

Each participant started with the baseline condition and was then randomly assigned to either sham first or orthosis first, resulting in two groups of equal subjects.

For each condition, participants performed seven tasks (static posture, wing-beat posture, finger-to-nose, spiral drawing, pouring, drinking, and eating) from the Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) scale in a clinical setting.

All tasks were video-recorded, allowing assessment of the TETRAS scale after the interventions. Accelerometry data were gathered from two IMUs placed on the wrist and hand of the participants.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
STIL anti-tremor orthosis

Primary outcome(s)

Measured at a single timepoint:
1. Tremor severity is measured using the TETRAS scale (score: 0-28), assessed by neurologists with specialization in movement disorders, for each intervention
2. Tremor power is measured using accelerometry data, recorded by two inertial movement units (IMU) located at the wrist and hand of the subjects, during each intervention

Key secondary outcome(s))
Measured at a single timepoint:
1. Patient satisfaction with the sham device and the orthosis, measured using the Dutch Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST), ranging on a scale from 1 (not at all satisfied) to 5 (very satisfied)
2. Adverse events, both reported by subjects as well as observed by the investigator

Completion date
19/10/2022

Eligibility

Key inclusion criteria
1. Diagnosed with essential tremor
2. Substantial perceived disability due to tremor in the arm, assessed from Bain and Findley ADL score (>30)
3. Tremor severity score >13 on subset (ADL tasks and upper-limb tasks) of the TETRAS scale
4. Dominant wrist flexion-extension and forearm pronation-supination tremor
5. Above 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Dominant shoulder internal-external rotation tremor
2. Dominant elbow flexion-extension tremor
3. Excessive alcohol consumption, as defined in the Dutch GGZ guidelines on alcohol use
4. Previous or planned deep brain stimulation (DBS) at the time of study enrollment that

interferes with testing
5. Previous or planned thalamotomy procedure, including stereotactic thalamotomy, gamma knife radio surgical thalamotomy, and focused ultrasound for the treatment of tremor at the time of study enrollment that interferes with testing
6. Change in medications related to tremor disorder in the 30 days prior to study enrollment
7. 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
8. Peripheral neuropathy affecting the tested upper extremity (e.g. carpal tunnel syndrome)
9. The suspicion or confirmation that head tremor may cause impairment in performing ADL tasks
10. Diagnosed Parkinson's disease, this includes the presence of parkinsonian features
11. Diagnosed functional tremor
12. Diagnosed physiologic tremor
13. Diagnosed cerebellar tremor
14. Diagnosed multiple sclerosis (MS)
15. Diagnosed ataxia
16. Patients with an amputation of one or both upper extremities.
17. Subjects with restricted movement or restricted muscle function in the arm and or hand (e.g. contractures)

Date of first enrolment
10/03/2022

Date of final enrolment
19/10/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Reinier de Graaf Gasthuis
Reinier de Graafweg 5
Delft
Netherlands
2625 AD

Sponsor information

Organisation
Reinier de Graaf Hospital

ROR
https://ror.org/00wkhef66

Funder(s)

Funder type
Other

Funder Name
Reinier de Graaf Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/01/2025	10/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.4		11/05/2023	No	No