Tremor in Dystonia and Essential tremor.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29165

Source
Nationaal Trial Register

Brief title
TREMOR-DTET

Health condition

English: Dystonic tremor, Dystonia, Essential tremor, tacs
Dutch: Tremor bij Dystonie, Dystonie, Essentiële tremor, tacs, beven

Sponsors and support

Primary sponsor: Donders Institute for Brain, Cognition and Behaviour. Centre for Cognitive Neuroimaging.
Kapittelweg 29 6525 EN Nijmegen
Source(s) of monetary or material Support: Hersenstichting (Dutch brain foundation)

Intervention

Outcome measures

Primary outcome

1) phase specific tremor power suppression during M1 tacs, in ET vs DT

2) phase specific tremor power suppression during Cerebellar tacs, in ET vs DT

3) Phase specific tremor related cerebral activity during cerebellar tacs, in ET vs DT

Secondary outcome

-Tremor related cerebral activity and connectivity, compared between dystonic and essential tremor.

-GABA concentrations in GPi, cerebellum and primary motor cortex, compared between dystonic and essential tremor.

Study description

Background summary

“In this study we will investigate whether frequency and phase specific transcranial alternating current stimulation (TACS) over the primary motor cortex and cerebellum influences tremor in dystonia and essential tremor. Outcome measures are tremor power (based on accelerometry) and tremor related cerebral activity and connectivity (combined TACS-fMRI). In addition, we will study the cerebral mechanisms underlying tremor in both disorders by using combined EMG-fMRI and GABA-MRS.”

Study objective

Reduced tremor power during transcranial alternating current stimulation over primary motor cortex (at tremor frequency and phase-locked to the ongoing tremor).

Study design

Not applicable, 2 visits for each participant, outcome measures divided over the two days.

Intervention

Transcranial alternating current stimulation (tacs) over primary motor cortex and cerebellum at tremor frequency and phase locked to ongoing tremor (as measured with accelerometry). Stimulation during 20 blocks of 30s, at 18 degree phase difference increments around the phase circle (random ordering, phase difference between ongoing tremor and tacs).

Contacts

Public
Freek Nieuwhof

Nijmegen
The Netherlands
Scientific
Freek Nieuwhof
Nijmegen
The Netherlands

Eligibility criteria

Inclusion criteria

Essential tremor:

-Clinical diagnosis of essential tremor

-Postural tremor of both hands

-Onset of tremor before the age of 65

Dystonic tremor:
-Clinical diagnosis of dystonic tremor
-Primary focal / segmental dystonia
-Presence of postural tremor of at least one arm (which may or may not be the dystonic limb)

Exclusion criteria

-Neurological co-morbidity

-Moderate to severe head tremor (to avoid artifacts caused by extensive head motion during scanning)

-Cognitive dysfunction (clinical diagnosis of mild cognitive impairment or dementia)

-Considerable diagnostic doubt between essential and dystonic tremor (no consensus reached in team meetings neurologists or considerable doubt in medical record).

-Use of anti-tremor medication other than propranolol

-Any contraindications for MRI or transcranial stimulation (e.g. non compatible metal implants, epilepsy, active implants).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2017
Application type:	First submission

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
NTR-new	NL6686
NTR-old	NTR6856
Other	NL60335.091.17 : HA2016-02-01

Study results

Summary results
N.A.