Tremography comparison of laboratory-grade and consumer product accelerometers in patients with essential tremor or Parkinson disease

Published: 30-05-2017
Last updated: 12-04-2024

To evaluate the validity of the peak frequency values and the amplitude at the peak frequency obtained from power spectral densities from the consumer product accelerometers and the laboratory-grade accelerometer following simultaneous tremor...

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

Summary

ID

NL-OMON45628

Source
ToetsingOnline

Brief title
Tremography comparison of accelerometers

Condition

- Movement disorders (incl parkinsonism)

Synonym
-

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research

Source(s) of monetary or material Support: Clinical Research Organisation,MakeHelsinki

Intervention

Keyword: Accelerometer, Essential tremor, Parkinson disease, Tremography

Outcome measures

Primary outcome

Validity of the peak frequency values and the amplitude at the peak frequency obtained from power spectral densities from the consumer product accelerometers and the laboratory-grade accelerometer will be described by agreement and reproducibility statistics for the norm of the 3-axes, and if needed for each axis separately.

Secondary outcome

N.A.

Study description

Background summary

Accelerometer advancements resulted in accelerometers being integrated into different consumer products, such as widely available smartphones. These sensors improved over the years in structure, sensitivity, resolution, g range, and working principle. Subsequently, medical applications (here forth indicated as apps) increasingly use the generated data from consumer product accelerometers to describe movement. Therefore, they may offer a cost-efficient and better accessible alternative for tremography and dyskinesia assessment compared to the laboratory-grade accelerometers.
There are several disadvantages to use the gold standard of tremor assessment, i.e. the laboratory-grade accelerometer. This method requires a research facility and trained clinical staff, thereby limiting the amount of assessments per day. The capacity to upscale the volume and ease of the assessments is small.
Several solutions can be found to circumvent the disadvantages of assessment with laboratory-grade accelerometers. In some studies, new devices were built to assess tremor at home in patients with essential tremor (ET) or Parkinson

disease (PD). Other studies used apps on smartphones to measure various patients with tremor.
Although these studies described tremor assessment by means of a smartphone, the methodology can be optimised, and new, improved, smartphones have entered the market. In a proof of principle study, only 1 PD and 2 ET patients were tested with an app developed for earthquake detection. Also, the iPhone type was not defined, the tremor assessment was not compared to laboratory-based accelerometer but to electromyography, and it did not represent daily use of a smartphone as the iPhone was strapped to a body part (either forearm or leg). Another proof of principle study only tested 4 patients (2 psychogenic tremor, 2 organic tremor), without describing the smartphone and app used or incorporating a control group or control measurement. In a different study the methodology was superior as tremor was compared between 21 PD patients and 21 healthy volunteers using the Samsung Galaxy SII with the Android Mobile app (Sensor UDP). However, the smartphone tremor assessment was not comparted with the gold standard laboratorium-grade accelerometer.
It remains unclear whether the data generated by these consumer products are comparable to data from the gold standard of laboratory-grade accelerometers such as used by de Haas et al. This is essential to investigate, as holding the consumer product with its specific shape and weight may affect the tremor(assessment) in patients with ET or PD. Thus, it is necessary to determine if and to what extent the tremor(assessment) is affected.
In this study we aim to obtain and compare data from accelerometers used in consumer products and laboratory-grade accelerometers. Data of both assessment types will be sampled simultaneously in 10 ET patients, and in 10 PD patients. The acquired data will enable validation and evaluation of the technical feasibility of the accelerometers in consumer products and improve the development of (multi-platform) tremography apps.

Study objective

To evaluate the validity of the peak frequency values and the amplitude at the peak frequency obtained from power spectral densities from the consumer product accelerometers and the laboratory-grade accelerometer following simultaneous tremor assessment in patients with ET or PD.

Study design

This is a validation study to compare consumer product accelerometers to laboratory-grade accelerometers in patients with ET or PD.

Study burden and risks

The potential risk associated with the repeated assessments including the movements to be executed (rest position with arms and hands horizontal, while elbows rest on chair, and with extended horizontal arms in frontal plane) is

muscle fatigue. These movements will last for 30 seconds. In total there will be 3.25 hours of measurements, including breaks. To limit the occurrence of muscle fatigue, subjects will have mandatory breaks of 2 minutes between each assessment. Around halfway during the study, a break of up to 1 hour is allowed, if needed.
All accelerometers are commercially available and will be used for their intended use: measuring acceleration.
There is no benefit for the subjects to participate in this study.

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

1. Signed informed consent prior to any study-mandated procedure;
2. Male or female subject, 18 to 80 years of age (inclusive);

a. Female participation is not limited to childbearing potential, or pregnancy or breast-feeding status;
3. A diagnosis of either ET or PD according to the following criteria:
a. ET diagnosis must fit the *classic ET* criteria, as describe by Deuschl et al. (Deuschl et al., 1998);
b. PD diagnosis must fit the *established PD* or *probable PD* level, as defined by Postuma et al. (Postuma et al., 2015);
i. Hoehn and Yahr stage must be * III;
4. Tremor must be present in at least 1 hand, regardless of the current therapy;
5. Otherwise healthy as is defined by absence of evidence of any active or chronic disease following a detailed medical and surgical history, and physical examination;
6. Body mass index between 18 and 30 kg/m2, inclusive, and with a minimum weight of 50 kg;
7. Ability to communicate well with the investigator in the Dutch language.

Exclusion criteria

1. Any known factor, concomitant diagnose(s) or disease(s) or condition(s), as judged by the investigator, that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in this study;
2. Unacceptable non-pharmacological therapies at screening, e.g., radiotherapy in a cancer study;
3. Unacceptable non-pharmacological use of substances at screening known or likely to interact with the study assessments (e.g., nicotine, alcohol, caffeine);
4. Positive test for alcohol or drugs of abuse at screening;
5. Participated in a clinical trial within 90 days of screening or more than 4 times in the previous year;
6. Unwillingness or inability to comply with the study protocol for any other reason, as judged by the investigator.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	30-05-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL60672.058.17