Development of a multimodal seizure detection instrument to improve safety and disease management of epilepsy patients at home

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON35980

Source
ToetsingOnline

Brief title
Nocturnal Seizure Detector

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: NWO

Intervention

Keyword: epilepsy, home care, nocturnal seizures, seizure detection

Outcome measures

Primary outcome

The outcome parameter is the performance (in terms of sensitivity and positive predictive value) of the MSDI against the gold standard of nocturnal video-EEG recording, so the association between seizures detected by the MSDI and seizures detected by video-EEG.

Secondary outcome

Secondary endpoints are:

(1) User friendliness measured by questionnaires on the valued aspects of the system and on potential objections.

(2) Inventory of the expectations of the performance of a seizure detection device from patients and caregivers and clinicians.

Study description

Background summary

Epilepsy is a chronic brain disease characterized by the unpredictable recurrence of seizures. We want to develop, validate and clinically evaluate a new multimodal seizure detection instrument (MSDI, see Fig 1) to alert for major epileptic seizures (generalized tonic-clonic, tonic, clonic, versive or hypermotor) during sleep at home or a sheltered home environment. This will provide a major step in patient safety, care, quality of life and disease management. Epilepsy is one of the most common neurological conditions. Its prevalence is 0.7% (120.000 people in the Netherlands), of whom 25% have regular, intractable seizures, especially children with epilepsy syndromes and patients with gross brain abnormality and cognitive impairments. About half of

seizures will be at night, posing problems in these vulnerable patient groups who depend on caregivers not sleeping in the same bed: parents taking care of their child, or nursing personnel in a sheltered home environment. In case of a major seizure, the caregiver has to intervene with medication, provide protection against injury or confusional wandering and give care for comfort. Development of automated home seizure detection systems is in its infancy, both scientifically and clinically. Presently, a reliable seizure detection and alert system at night is lacking. Combined EEG-video is the gold standard for in-hospital seizure detection. EEG, however, is unsuitable at home, as it is liable to artefact, requires expert interpretation and is uncomfortable. Home detection currently consists of unreliable audio-alarms. Thus, many nocturnal epileptic seizures will go unnoticed, and false alarms occur due to snoring and other noises. Caregivers do not like to depend on audio-alarms if the security of the patient is not guaranteed, and will decide to sleep in the same room, disrupting parental life and potentially hamper the development of autonomy of the child, or rely on professional care which is costly and also without instruments. In this project we have developed a new MSDI device using an optimized combination of non EEG sensors. Preliminary studies led us to select 4 modalities: audio, automated video frame analysis, heart rate and 3D accelerometry, yielding 10 output variables. We expect that, rather than relying on one modality, combining modalities will reduce the number of false positive and false negative alerts.

Study objective

The overall main objective is to develop an optimal combination of sensors and techniques to detect major nocturnal seizures with high sensitivity and specificity in an extramural setting. The study we present here (which is phase 2 out of 3 of the development process) focuses on: a) optimizing existing techniques and algorithms, especially related to motion sensing; b) optimizing sensitivity and specificity of the combined technology of heart rate variation, accelerometry, audiometry and video frame analysis in a large group of in-hospital patients using the gold standard of combined video-EEG.

Study design

The whole project is divided into 3 phases; the current study relates to phase 2. In phase 1 we have perfected the technology and algorithms of the individual modalities and built the MSDI. In this protocol, we describe phase 2 of the development process, in which we will test the MSDI in the target population (n=100) by in-hospital sampling its output simultaneous with the gold standard of clinical EEG-video. We will then optimize the settings of output variables to obtain a maximum ROC with sufficient sensitivity (e.g. 90%) and specificity (e.g. 75% positive predictive value). In phase 3 we will check the performance of the device at home (n=40) by comparison with the home gold standard of video observation, and assess the technical feasibility, compliance, effects on

well-being and implementation of the device into novel care models. The phase 3 study will be presented to the METC in a later stage. During phase 2 and 3, end-users are involved in development, implementation, practical and privacy issues. We will address ethical implications of the use of the device and the moral aspects of the development and introduction of this technology which will influence the behaviour and experiences of users.

Study burden and risks

The multimodal seizure detection device will run along with clinical video-EEG registration during the night. The system hardware consists of:
(a) video-audio: this will run independently from the professional video-audio that is part of the clinical video-EEG recording system. Hardware consists of a commercial digital camrecorder that is mounted on a standard in the corner of the sleeping room and is plugged into the power net. Output will be saved on the hard disk of the MSDI laptop.
(b) ECG and accelerometry: this is a 3-lead system with sensors on the chest and on both upper arms. The upper arm units are attached by 2 elastic fasteners with the units directed anteriorly, laterally or posteriorly according to the wishes of the patient. One of the sensors is also a wireless transmittor that sends output to:
(c) the MSDI laptop, which is stored in a cupboard in a corner of the room.
During phase 2 of the study all algorithms will be applied offline after data acquisition. An online alarm is therefore not part of the system at this stage.
The main risk of the system is that the upper arm sensors somehow interfere with normal sleep, or that the ECG electrodes cause an allergic skin reaction. In these cases, the sensors will be removed.
The ECG electrodes are standard electrodes, and the accelerometry units are CE certified. The MSDI will also be tested and approved before clinical use by the technical department of the UMC Utrecht.
Risk is therefore negligible.
Benefits for the patient will be small if any, and might consist of an MSDI-detected seizure during the night that was missed by the clinicians while reviewing the clinical video-EEG registration.
Projected benefits may be large when the MSDI will prove successful at the end of the study and the patient may be in the target population for the final MSDI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients with refractory epilepsy and nocturnal seizures who are referred for clinical video-EEG seizure recordings to the epilepsy monitoring unit of one of the participating centers.

Exclusion criteria

Self-reported nocturnal seizure frequency must be at least 1 per week. The patient or parents/legal representatives must be capable of understanding Dutch and filling in questionnaires, and must be able to provide informed consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2012
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	multimodal seizure detection instrument
Registration:	No

Ethics review

Approved WMO

Date:	27-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37248.041.11