A mini EEG for the detection of delirium superimposed on dementia; A proof of concept study.

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Detection of delirium superimposed on pre-existing cognitive impairment or clinically manifest dementia (DSCID) is extremely challenging. As a direct consequence of these diagnostic difficulties patients tend to be misdiagnosed and thus mistreated....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Deliria (incl confusion)
Study type	Observational non invasive

Summary

ID

NL-OMON45297

Source
ToetsingOnline

Brief title
Mini EEG in DSD

Condition

- Deliria (incl confusion)

Synonym
confusion, dearrangement

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Dijk en Duin (Castricum)
Source(s) of monetary or material Support: Weston Brain Institute;Toronto;Canada. De toewijzing is gedaan door iemand die niet onderdeel was van de onderzoeksgroep.

Intervention

Keyword: Delirium, Dementia, Elderly, Electroencephalography (EEG)

Outcome measures

Primary outcome

The primary endpoint in this study is *delirium* or *no delirium* classified by the reference standard. The reference or golden standard will be based on the registrations with the camera, which will be evaluated by two or three golden standard specialists, namely geriatricians, psychologists, neurologists or psychiatrists, all with experience in delirium to obtain a reliable diagnosis of the patients using DSM-V criteria. Together with the information from the clinical observational scales and patients* medical files, this will lead to a conclusion on the diagnosis: delirious, non-delirious, or possible delirious.
The main study parameters will be the sensitivity, specificity, and predictive values based of each mini EEG in the eyes open and the eyes closed condition (index test) compared to the reference standard (i.e., classification by delirium expert).

Secondary outcome

Secondary study parameters/endpoints (if applicable)

i. The association between the output of the EEG monitor and the scores of the observational scales used.

ii. Discomfort during mini EEG monitor registration periods.

Other study parameters (if applicable)

The following characteristics will be collected from the medical chart:

i. Age

ii. Sex

iii. History of neurological or psychiatric disease

iv. Psycho-active medication use (including anti-epileptic, anti-psychotics, or benzodiazepines) in the preceding 24 hours.

v. Pre-existent cognitive impairment

The following characteristics during recording with the EEG monitor will be described:

i. Medication use during registration, specifically: psycho-active medication (including benzodiazepines) used in the last 24 hours

ii. Number of times that recording with delirium monitor was not feasible and the reason why

iii. Current suspected infectious disease, confirmed with positive cultures.

Study description

Background summary

Delirium, also known as acute confusional state, poses unique challenges in patients with cognitive impairment or clinically manifest dementia. It causes immediate and extensive suffering in patients, distress in caregivers, and health care staff. While the diagnosis of delirium can be difficult in otherwise healthy older persons, detection of delirium superimposed on pre-existing cognitive impairment or clinically manifest dementia (DSCID) is extremely challenging. In this patient population it is difficult to accurately distinguish the cardinal signs of delirium, i.e. newly occurring changes in attention and cognition and a fluctuating clinical course, from signs of pre-existing cognitive impairments or dementia. Moreover, from a clinical point of view, distinguishing subtle changes in orientation, memory, executive functions and behavior from pre-existing cognitive impairments is extremely

difficult, if not to say impossible given the currently provided diagnostic scales. As a direct consequence of these diagnostic difficulties patients tend to be misdiagnosed and thus mistreated, and are often prescribed psychotropic medications without adequate assessment or more appropriate non/pharmacological counseling. Therefore, reliance on clinical assessment for the diagnosis of DSCID may be suboptimal.
These considerations have sparked researchers to increase diagnostic accuracy by using more objective information that rely on electroencephalography (EEG). Classical literature, dating back 60 to 70 years, strongly suggests already that electroencephalography (EEG) can distinguish between delirium and non-delirium using EEG frequency band parameters. More recent research confirms these findings by investigating whether maintenance of activation (eyes open) assessed by EEG discriminates delirium in association with dementia from dementia without delirium and cognitively unimpaired elderly subjects. However, standard EEG recordings, applying 25 electrodes, taking 20 minutes or more, in a neurophysiology lab with specialized recording facilities, are not feasible in DSCID populations. Recent studies by the group of prof. Slooter et al. in postoperative patients have shown that it is possible to reliably detect delirium using only a four electrode EEG recording (reference electrode, and three recording electrodes), of less than 10 minutes with bedside, automatic processing based on the relative power in de delta and theta frequency band. A pilot study in the target population (VUMC-METC 2015.408) documented that wearing this tiny EEG device was not associated with any additional discomfort compared to mere clinical observation.
In our current study, this promising, innovative bedside mini EEG monitor with automatic processing will be evaluated in a proof of concept study for the early and reliable detection of delirium in patients with cognitive impairment or clinically manifest dementia. Ultimately an improved diagnosis of delirium in these patients will facilitate early treatment and prevention of subsequent cognitive deterioration.

Study objective

Detection of delirium superimposed on pre-existing cognitive impairment or clinically manifest dementia (DSCID) is extremely challenging. As a direct consequence of these diagnostic difficulties patients tend to be misdiagnosed and thus mistreated.
In our current study, an innovative bedside mini EEG monitor with automatic processing will be evaluated in a proof of concept study for the early and reliable detection of delirium in patients with cognitive impairment or clinically manifest dementia. Ultimately an improved diagnosis of delirium in these patients will facilitate early treatment and prevention of subsequent cognitive deterioration.

Study design

The study is a Prospective cohort observational study.

All patients together with their legal representatives, who belong to the above defined source population, and who fulfil inclusion criteria, but none of the exclusion criteria, will be informed about this study by a member of the research team. The patients, or their legal representative, will be asked to sign informed consent. After informed consent is received, the patient will be given a study number based on chronological order of admission.

The first measurement (T1) takes place as soon as possible, yet at least one week after
admission. Both a 5 minutes eyes-open, and 5 minutes eyes-closed EEG-monitor recording will be conducted, while the patient is observed for signs of discomfort, using the Discomfort Scale * Dementia of the Alzheimer Type (DS-DAT). This will be used as baseline measure.

Within the same hour of this recording, after removing the electrodes, a standardized clinical screening according to the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) and the Observational Scale of Level of Arousal (OSLA), and will be recorded on digital video. Patients will be examined for presence or absence of a possible delirium using the DSM-V criteria by a member of the research team (blinded for the mini EEG monitor result). Finally a clinical conclusion 1) delirious, 2) possibly delirious, 3) not delirious will be documented.
To overcome an order effect of activation, the patients will be randomized for order of assessments: half of the participants will first undergo the mini EEG after which the CAM-ICU will be assessed and the other half will first be assessed according to the CAM-ICU, after which they will undergo the mini EEG. When patients have a delier during their stay in the clinic, they will undergo a maximum of three more measurements (T2,T3,T4=within measurements), at least seven days after T1. All participating patients will have a last measurement at about one week before discharge (T5=end measurement). Discharge takes place when there is no longer any susceptibility of possible delirium.

The researcher who will be analyzing the mini EEG registrations will be blinded for the classification made by the delirium experts, as described below, and the delirium experts will be blinded for the results of the mini EEG monitor. Furthermore, all treating doctors and nursing specialists will be blinded for the results of the mini EEG monitor.

From our previous study we learned that EEG recordings in delirious patients are feasible without problems. The delirium monitor will make use of only four electrodes instead of 25, and is designed to have optimal usability.

Study burden and risks

A maximum of 5 measurements with the EEG device will take place. Each EEG

measurement takes place for 10 minutes maximal. The patients will be observed while wearing the EEG device (see Figure 1). The patient will be asked to keep his/her eyes open for 5 minutes followed by 5 minutes eyes closed. There will be no forcing, yet a neutral and natural situation will be created. Thereafter, the headband with four electrodes will be removed. The length of the total observation period will be taylor-made, depending on patients* (dis)comfort. Rest periods will be introduced while necessary. Measurements will be stopped earlier when signs of large discomfort are observed.
There will be a group-related benefit, as development of an objective tool for delirium detection superimposed on dementia may improve treatment of delirium and therefore outcome.

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

All admitted patients will be invited to participate in this study. In order to be eligible to participate, the patient and their legal representative must provide informed consent.

Exclusion criteria

A person who will meet any of the following criteria will be excluded from participation in this study: Isolation because of known carrier ship of a resistant bacterium.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL59734.029.16