Validation of a delirium monitor in postoperative elderly patients

Published: 20-03-2014
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The research objective is to investigate the sensitivity, specificity, and predictive values of the delirium monitor based on 4 standardized EEG electrodes who record brain activity.

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

Summary

ID

NL-OMON44951

Source
ToetsingOnline

Brief title
Validation of delirium monitor

Condition

- Deliria (incl confusion)

Synonym
confusion, Delirium

Research involving
Human

Sponsors and support

Primary sponsor: Intensive Care Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Delirium, Elderly, Electroencephalography, Postoperative

Outcome measures

Primary outcome

The primary study parameters are the sensitivity, specificity, and predictive values based on the Receiver Operating Characteristics (ROC) curve of the relative delta power with as reference standard the diagnosis delirium by the delirium expert.

Secondary outcome

- Relative delta power vs. DRS-R-98 (measure of severity of delirium)

- Relative delta power vs. VAS (0-10) likelihood for a patient to be delirious

- Impact of measurement for patient based on a two-question questionnaire

- Burden of measure between 0 (no burden) and 10 (unimaginable burden)

- Duration of measurement between 0 (fine) and 10 (too long)

Study description

Background summary

Delirium is an acute disturbance of consciousness and cognition that tends to fluctuates over time. It is a common disorder in hospitalized patients, especially in postoperative elderly, with a reported incidence between 4% and 65% after major surgery. Delirium is associated with higher mortality, longer hospital stay, long-term cognitive impairment, and increased costs. Despite its frequency and impact, recognition of delirium by physicians (30-50%) is poor. Various delirium assessment tools have been developed for use by non-psychiatric personnel such as the confusion assessment method (CAM) and delirium observation scale (DOS). These scales are applicable in research setting, however in clinical practice some delirious patients were still missed. Therefore, an objective detection tool is needed to monitor delirium. From previous literature we know that electroencephalography (EEG) can distinguish patient with and without using certain EEG parameters. Besides, it was shown that it is possible to use only four electrodes (reference electrode, and three recording electrodes) of the EEG recordings to detect delirium. This resulted in the development of a prototype of an EEG-based delirium monitor,

based on a standardized EEG recording with only 4 electrodes.

Study objective

The research objective is to investigate the sensitivity, specificity, and predictive values of the delirium monitor based on 4 standardized EEG electrodes who record brain activity.

Study design

This study is an observational, mono-center study with repeated diagnostic measurements which will be performed in the University Medical Center Utrecht (main center), Radboud University Medical Center in Nijmegen, Isala Klinieken in Zwolle and Charité Universitätmedizin in Berlin.

Study burden and risks

No risks are expected for recordings with the delirium monitor, because the delirium monitor is based on a standardized EEG recording. EEG recordings are performed without any risks.
The burden of the measurement is estimated as low. A maximum of 3 simple EEG measurements with 4 electrodes of maximal 7 minutes will be performed. Furthermore, a maximum of 3 evaluations of the DRS-R-98 and VAS score by the delirium expert, will be conducted on 3 days. The electrodes will be fixed with gel without any harm. Removal of the electrodes is also harmless and no hair is needed to be shaved. The patient has to keep the eyes open for two minutes followed by 5 minutes eyes closed during the registration with the EEG monitor. The psychiatric evaluation will be recorded on video which will be evaluated by a gold standard (neurologist, geriatrician, or psychiatrist).

From our previous study we know that a complete EEG recording in delirious patients is feasible without any problems. The delirium monitor will only make use of four electrodes instead of 25, and is designed to have optimal usability. However, if a patient is objecting, for example verbally or by pulling the electrodes, we will remove the electrodes immediately and suspend the registration.

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

Aged 60 years and older
Patients undergoing elective surgery in UMC Utrecht, Isala Klinieken in Zwolle, RadboudUMC in Nijmegen, or Charité Universitätmedizin in Berlin
Expected to stay at least 2 days in hospital after surgery.
Patients defined as frail according to the geriatrician

Exclusion criteria

No communication possible due to language barrier or deafness
Admission for neurological surgery
Participation in this study during a previous hospital admission
Practical or logistical reasons hampering the use of the delirium monitor
Isolation because of known carrier ship of a resistant bacterium

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2014
Enrollment:	114
Type:	Actual

Medical products/devices used

Generic name:	Positioning aid for EEG electrodes
Registration:	No

Ethics review

Approved WMO Date:	20-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-02-2016

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-06-2016
Application type:	Amendment
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	NL46622.041.13