EEG characteristics of delirium in cardiothoracic surgery patients

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To determine the differences in EEG properties between delirious and non-delirious (ICU) cardiothoracic surgery patients surgery and to determine the EEG deviation where the largest differences appear. Secondary objective is to determine the...

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

Summary

ID

NL-OMON38344

Source
ToetsingOnline

Brief title
EEG characteristics of delirium

Condition

- Deliria (incl confusion)

Synonym
delirium, delusional

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardio-thoracic surgery patients, Delirium, Electroencephalography

Outcome measures

Primary outcome

The folowing EEG properties are calculated for different EEG deviations:

the absolute power of delta (0.5-4), theta (4-8 Hz), alpha (8-13 Hz) and beta (13-20 Hz);

the relative power (% of total power of EEG) of delta (0.5-4), theta (4-8 Hz), alpha (8-13 Hz) and beta (13-20 Hz);

the peak power;

the mean power;

the peak frequency

the centroid frequency.

Secondary outcome

Results of the psychotic symptoms questionnaire

Results of the evaluationform

Study description

Background summary

Delirium is a common disorder in the intensive care unit (ICU), with a reported incidence up to 80%. However, delirium is poorly recognized. In previous studies, electroencephalography (EEG) appeared to be a sensitive tool for the diagnosis of delirium. However, this knowledge was never implemented in a continuous monitoring system. Before a continuous monitoring system can be developed, it is important to determine which EEG characteristics are most affected affected and at which EEG deviation they are most affected. To study EEG characteristics we first focus on a uniform population of cardiothoracic

surgery patients. Furthermore we want to study the feasibility of a psychotic symptom questionnaire, because psychotic symptoms can be related to eye movements, which can also be measured by EEG.

Study objective

To determine the differences in EEG properties between delirious and non-delirious (ICU) cardiothoracic surgery patients surgery and to determine the EEG deviation where the largest differences appear. Secondary objective is to determine the feasibility of the psychotic symptoms questionnaire in 11 delirious patients.

Study design

The study design is a prospective, descriptive, diagnostic study.

Study burden and risks

For the majority of patients the only burden is a standard, 30 minute EEG. However, eleven delirious patients will also receive an orally administered questionnaire which will take approximately 2-10 minutes. The questionnaire will be administered during the EEG preparation, and therefore will not add extra time to the investigation. As there are no risks and small benefits for the individual patient, the risk-benefit is positive. Delirious patients that participate in this study can be diagnosed with non-convulsive epileptic seizures and receive on time an adequate treatment, which otherwise could be delayed.
The goal of this study is to find EEG parameters which are specific for delirium. These EEG parameters can be used to diagnose delirium more adequately and thereby guide to better treatment of these patients. Without participation of patients with delirium it is not possible to determine EEG parameters which can be used for diagnosing delirium. Therefore, this study is group-related.

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

Patients admitted in the University Medical Centre Utrecht after cardiothoracic surgery.
informed consent

Exclusion criteria

No informed consent
Other cerebral disorder than delirium
RASS score lower than -3
Use of haloperidol is not an exclusion criterion.

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):	12-09-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-12-2012
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	NL35576.041.11