Pilot study for classification of attempted movement from the electroencephalogram in healthy participants with a temporary paralysis of one arm induced by local administration of rocuronium

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37183

Source
ToetsingOnline

Brief title
Attempted movement in EEG

Condition

- Other condition

Synonym
monitoring during anesthesia

Health condition

perioperatieve monitoring

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW (NWO)

Intervention

Keyword: Attempted Movement, Brain-Computer Interface, Electroencephalogram, Neuromuscular Blocking Agent

Outcome measures

Primary outcome

The main study parameter is the classification rate of our algorithm, i.e. the percentage of movement trials that are correctly classified as movement trials and the percentage of non-movement trials that are correctly classified as non-movement trials.

Although the algorithm is programmed in such a way that it can take into account any feature from the EEG that distinguishes between the two classes, we expect the main useful feature to be the combined Event-Related Desynchronization (ERD), a power decrease in the alpha- and beta-frequency bands known to occur during (planning) of movement and Event-Related Synchronization (ERS), a power increase in approximately the same frequencies, known to occur after movement has stopped. These features have been well established in the literature and these findings have been replicated in our own lab.

Secondary outcome

As also EMG and the level of neuromuscular blockade (train-of four monitoring)

will be measured throughout the experiment, insight might be gained into the

influence of rocuronium on EMG and the level of neuromuscular blockade

(train-of four monitoring) and the interplay between them.

Study description

Background summary

Awareness during anesthesia is defined as consciousness during surgery and recall of intraoperative events when general anesthesia was intended, possibly leading to intra-operative pain, panic and anxiety. Whereas the main cause for awareness is an insufficient depth of anesthesia (Ghoneim et al., 2009), possible undesired consequences also exist for the opposite case of too deep anesthesia, e.g. hypotension and longer durations of recovery (Kent & Domino, 2009). This means there is only a narrow adequate range of depth of anesthesia, hence administration should be carefully monitored. However, anesthetic depth is not a single measurable variable, rather a complex reflection of the state of the central nervous system. In addition to more traditional ways of monitoring depth of anesthesia, such as measurement of changes in blood pressure, heart rate, sweating and tear production, several types of EEG-based monitoring devices have been introduced, e.g. the Bispectral Index (BIS, Aspect Medical Systems, Massachusetts) and the Entropy Module (GE Healthcare, Helsinki). Despite these developments, unintended awareness during general anesthesia is still an unresolved issue with a current incidence of 0.1 to 0.2%, amounting to approximately 26,000 cases annually in the United States alone (Sebel et al., 2004).

General anesthesia involves the simultaneous administration of different components including neuromuscular blocking agents for immobilization. As a consequence of this induced paralysis, patients trying to move in order to alert the surgeon or anesthetist when awareness occurs fail repeatedly (Ghoneim et al., 2009, Sandin et al., 2000). Obvious parallels can be drawn with patients who are (partly) paralyzed by disease and for whom new methods of communication are currently under development. In certain Brain-Computer Interface (BCI) paradigms, frequency information in the EEG signal over the motor cortex during (imagined) movement or planning of (imagined) movement is used to create interaction between the user and a computer or other device (Pfurtscheller & Neuper, 2006).

Based on this principle, we propose the development of a monitor of

intraoperative awareness by means of detecting attempts to move. In the proposed paradigm the event-related desynchronization (ERD) and -synchronization (ERS), features commonly used in movement-based BCI's, will be exploited to detect a patient's urge to move and therefore function as input to a 'brain switch' type monitor.

Study objective

Previous investigations in our lab have provided insight in the requirements for development of such a system and shown the feasibility of the paradigm (Blokland et al., 2011). We have been able to optimize the settings of our proposed system to such an extent that it is both fast and accurate. All research until now has however focused on healthy, unanesthetized participants only, performing either actual or imagined movement. To get a full understanding of the applicability of the paradigm during general anesthesia, we first need to determine how reliably attempted movement can be detected when actual motor output is blocked. The aim of the present study is to investigate how well our developed system is able to detect attempted movements from participants of whom one arm is temporarily paralyzed by means of administration of a neuromuscular blocking agent.

We hypothesize that attempted but pharmacologically blocked movement can be detected from EEG (i.e., with a classification rate higher than chance), possibly as well as imagined movement or even isometric movement.

By recording the EEG from participants instructed to attempt hand movement even though motor output is blocked, it can be tested whether our system is able to reliably detect these attempted movements.

Study design

In an observational study consisting of a single session per subject (lasting at most three and a half hours), the electroencephalogram (EEG) will be measured while the subject performs several movement tasks, both before and after administration of a neuromuscular block (rocuronium) to one arm isolated with a tourniquet. For a more elaborate study design please see chapters 3 and 6 of the research protocol.

Study burden and risks

Participation involves one session of at most three and a half hours, including EEG montage and measurement, as well as administration of a neuromuscular block to one arm isolated with a tourniquet.

Possible risks of participation in this study are:

-iv-needle: pain, hematoma, infection
-tourniquet: pain, nerve or tissue damage through local pressure or ischemia. Important to note here is the fact that tourniquets are regularly used for up to 2 hours during surgery if the surgeon wants to operate bloodlessly on an extremity; with the short use we are intending, risks are minimal.
-Rocuronium: allergic reactions, systemic muscle relaxant effects
-Suggamadex: allergic reactions

All risks are considered relatively unlikely to occur.
Although the procedures might make participants feel uncomfortable at times, they are not considered harmful.

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

-18-65 years old
-right-handed
-normal or corrected to normal vision
-normal or corrected to normal hearing

Exclusion criteria

-neurological impairment
-motor disabilities
-known allergies to Rocuronium and/or Sugammadex
-regular drug intake
-hypertension

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Rocuronium bromide
Generic name:	Rocuronium bromide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2012-001777-86-NL
CCMO	NL40922.091.12