Evaluation of an electronic device to objectively monitor energy expenditure, physical activity, unrest and autonomic nervous system function in patients admitted to the Intensive Care

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The objective of the study is to explore the performance of the Sensewear device during various levels of activation of the autonomic nervous system and sedation in a population patients admitted to an ICU.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31133

Source
ToetsingOnline

Brief title
Evaluation of a Sensewear device at the ICU

Condition

- Other condition
- Cardiac therapeutic procedures

Synonym
consciousness, sedation

Health condition

sedatie op ICU, nav mechanische beademing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: autonomic nervous system, ICU, monitoring, sedation

Outcome measures

Primary outcome

For the study part where patients are undergoing elective cardiosurgery, the primary study parameter will be the function of the autonomic nervous system, which can be evaluated by measurements of the galvanic skin response (with the Sensewear device) and heart rate variability.

For the study part where other ICu patients are studied, the primary study parameter will be the depth of sedation, which can be evaluated by measurements of BIS registration and acceleration (with the Sensewear device0.

Secondary outcome

For both groups of patients, the secundary study parameters will be the other parameters of autonomic nervous system function as measured with the Sensewear device.

Study description

Background summary

Patients admitted to an Intensive Care Unit are well-monitored to evaluate their clinical condition. Although in general the so-called vital signs (blood

pressure, heart rate and temperature) are well monitored, there is a paucity of information on other relevant parameters. This includes, among others, information on the amount of energy expenditure and scoring of physical activity. Recent technological developments have resulted in the introduction of small electronic devices (such as the SenseWear® armband) that provide non-invasive measures of total energy expenditure and physical activity. This is based upon recording of skin temperature, the galvanic skin response, the heat flux and accelerometry.

Study objective

The objective of the study is to explore the performance of the Sensewear device during various levels of activation of the autonomic nervous system and sedation in a population patients admitted to an ICU.

Study design

Outline of study activities cardiosurgery patients: Eligible patients will undergo the scheduled surgical procedure. The only deviation from the routine care is that an armband with the device will be strapped around their right upper arm. The armband will be applied for one hour at the evening before surgery and for a period of 24 hours that will start when the patient is transferred to the surgery room. Most patients are already commonly monitored using a BIS-monitor and special attention will be given that all patients participating in this study will have such a monitor. Also, in these patients 1-lead ECG recordings will be made which will enable to study the Heart Rate Variability, which is considered a measure for the activity of the autonomic nervous system.
Outline of study activities ICU patients: Eligible patients will, during the routine care, be equipped with an armband with the device strapped around their right upper arm. The armband will be applied for periods of 24 hours. Most patients are already commonly monitored using a BIS-monitor and special attention will be given that all patients participating in this study will have such a monitor.

Study burden and risks

As this experiment is carried out during the routine medical care of the patients, this implies that all procedures and activities necessary for the care of the patients will not be altered, so participation in the study will have minimal burden and risks.

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

20 patients scheduled for elective cardiosurgery.
20 patients admitted to the ICU and are receiving sedation medication.

Exclusion criteria

Patients treated with a pacemaker

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL16686.058.07