Sleep and biorhythm in ICU patients: a pilot study

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To investigate the incidence and severity of disturbed biorhythm among ICU patients, and the effect on quality of sleep. We also aim to validate the novel ICU Depth Of Sleep (IDOS) index in detecting depth of sleep over time. Secondarily: we will...

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

Summary

ID

NL-OMON43659

Source
ToetsingOnline

Brief title
Sleep and biorhythm in the ICU

Condition

- Other condition
- Sleep disturbances (incl subtypes)

Synonym
Disturbed biorhythm, disturbed sleep

Health condition

verstoorde secretie van melatonine

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Ministerie van OC&W,Philips Research

Intervention

Keyword: Biorhythm, Intensive Care Unit, Melatonin, Sleep

Outcome measures

Primary outcome

Correlation between sleep continuity and amplitude of melatonin secretion

Interrater agreement between methods of sleep analysis (defined by Cohen*s

Kappa):

o R&K analysis and IDOS index

o Somnolyzer score and IDOS index

o Actigraphy and IDOS index

Sleep-related parameters (using EEG: Rechtschaffen & Kales (R&K) manual

scoring, and IDOS method):

o total sleep time (any sleep stage other than awake, EEG)

o number of awakenings and arousals

o sleep efficiency

o sleep continuity

Biorhythm:

o time and amplitude of concentration of melatonin secretion

o minimum melatonin concentration

o difference between peak and minimum

Secondary outcome

Cognitive and behavioural parameters:

o ICU delirium by CAM-ICU

o ICU delirium manifestation type defined by RASS-scores65 (hypo/hyperactive,

or mixed)

o duration of ICU delirium

o clinical requirement for pharmacological intervention (haloperidol)

Environmental parameters:

o light levels (lux)

o light frequencies

o noise levels (decibel), and number of peaks exceeding 65dB

o temperature (degrees Celsius)

ICU and hospital length of stay

Mortality (until ICU discharge, hospital discharge, 6 and 12 months after

hospital discharge)

Amount of administered opioids, benzodiazepines, sedatives and antipsychotics

Study description

Background summary

Metabolic disturbances associated with critical illness may disturb secretion of melatonin, the most important factor for circadian timekeeping. This disturbance may in turn hamper distribution and high quality sleep, with potentially detrimental effects on patient cognition and behaviour.

Study objective

To investigate the incidence and severity of disturbed biorhythm among ICU patients, and the effect on quality of sleep. We also aim to validate the novel ICU Depth Of Sleep (IDOS) index in detecting depth of sleep over time.

Secondarily: we will determine the incidence, duration and severity of disturbed sleep and delirium among ICU patients.

Study design

Prospective observational pilot study

Study burden and risks

There is no foreseeable risk involved with participation in this observational pilot study. The greater majority of ICU patients undergo frequent blood withdrawal from indwelling catheters for routine measurements. Participation in this study will marginally increase the total amount of blood taken, while also utilizing irregularly sampled blood from routine measurements. This additional material provides more data without increasing the burden on ICU patients.

Contacts

Public
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Scientific
Philips

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

ICU patients
> 18 years of age
Expected stay in the ICU 48h or longer
Capable of understanding and speaking Dutch
Richmond agitation and sedation scale (RASS) * -3

Exclusion criteria

Pre-existing history or treatment of sleep pathology, severe visual or hearing impairment, alcohol addiction or illicit drug abuse
History of cognitive dysfunction (defined as dementia, traumatic brain injury, stroke or hepatic encephalopathy)
Previously discharged from the ICU during this hospital admission
Admission following neurosurgery (since underlying pathology, or the surgery itself, may interfere with sleep and cognitive function)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2015
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	04-08-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	22-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-01-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL52427.042.15