Sleep and biorhythm in the ICU

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26764

Source
Nationaal Trial Register

Brief title
Sleep-ICU

Health condition

Melatonin secretion, quality of sleep, incidence of delirium.

Sponsors and support

Primary sponsor: PERFORMER
Department of Critical Care
(in Dutch: Intensive Care Volwassenen)
University Medical Center Groningen
Hanzeplein 1, 9700 RB Groningen
The Netherlands
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SPONSOR
Patient Care & Measurements
Philips Research Eindhoven
High Tech Campus 34, 5656 AE Eindhoven
The Netherlands
Tel: +31 40 2742370
Source(s) of monetary or material Support: Department of Critical Care
(in Dutch: Intensive Care Volwassenen)
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Patient Care & Measurements
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Intervention

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

Sleeprelated
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 CAMICU

o ICU delirium manifestation type defined by RASSscores65
(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

Background of the study:

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.

Objective of the study:

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 population:

50 adult ICU patients with an expected stay of >48 hours in the ICU of the UMCG.

Primary study parameters/outcome of the study:
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

Sleeprelated
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

Secundary study parameters/outcome of the study (if applicable):

Cognitive and behavioural parameters:

o ICU delirium by CAMICU

o ICU delirium manifestation type defined by RASSscores65
(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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if
applicable):

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.

Study objective

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 design

24 hours after admission to the ICU, with a maximum inclusion duration of 72 hours.

Intervention

- none

Contacts

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Eligibility criteria

Inclusion criteria

ICU patients

Capable of giving informed consent

> 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

Preexisting
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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2015
Application type:	First submission

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
NTR-new	NL5197
NTR-old	NTR5345
Other	ABR NL52427.042.15 : METC 2015.134

Study results

Summary results

Reinke, L., van der Hoeven, J. H., van Putten, M. J., Dieperink, W. & Tulleken, J. E. Intensive care unit depth of sleep: proof of concept of a simple electroencephalography index in the non-sedated. Crit. Care 18, R66 (2014).