Sleep and biorhythm in the ICU

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26764

Bron
Nationaal Trial Register

Verkorte titel
Sleep-ICU

Aandoening

Melatonin secretion, quality of sleep, incidence of delirium.

Ondersteuning

Primaire sponsor: PERFORMER
Department of Critical Care
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- none

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5197
NTR-old	NTR5345
Ander register	ABR NL52427.042.15 : METC 2015.134

Resultaten

Samenvatting resultaten

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).