# Measuring quality of sleep in critically ill patients in the ICU: A pilot study

Published: 23-07-2012
Last updated: 26-04-2024

Objective: In this pilot study experience will be obtained in the simultaneous use of PSG, melatonin assay, CBT-measurement and assessment in ICU patients.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Sleep disturbances (incl subtypes) |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON36890

**Source**
ToetsingOnline

**Brief title**
Measuring quality of sleep in the ICU

### Condition

- Sleep disturbances (incl subtypes)
- Deliria (incl confusion)

**Synonym**
delirium, quality of sleep

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Circadian rhythm, ICU, Quality, Sleep

## Outcome measures

### Primary outcome

Main study parameters/endpoints: The main study parameters will be the total sleep time (TST), percentage of TST spent in Rapid Eye Movement (REM) sleep, percentage of TST spent in stage 1-2 and stage 3-4 Non REM sleep, the number of awakenings and the number of arousals.

### Secondary outcome

Best fit coefficients of circadian rhythm models are compared between melatonin assay and CBT. Incidence of delirium is determined through the Confusion Assessment Method for the ICU (CAM-ICU) observation scale.

# Study description

### Background summary

Rationale: Sleep deprivation is known to lead to several clinical and physiologic manifestations also found in delirium; however, its role in the development of delirium in the intensive care unit (ICU) is controversial. Delirium in the ICU is among others associated with sleep deprivation, quality of sleep and perhaps caused by a disrupted circadian rhythm.
This circadian rhythm is normally found in many physiological processes in healthy individuals and can be easily determined by measurement of core body temperature (CBT) following a 24-hours cycle and melatonin levels. In ICU patients this rhythm is known to be disturbed or even abolished.1-4 It is important to know if or to what extend the sleep of the patients at the intensive care is affected or adversely influenced, and if this is of influence on the incidence of delirium. Future interventional studies will focus on methods to improve circadian rhythm to minimize sleep deprivation and incidence of delirium.
First the feasibility of the proposed method of quantifying and qualifying sleep through polysomnography (PSG) and simultaneously determining

circadian rhythm through blood melatonin assay and CBT-measurement, needs to be investigated in a pilot study.

### Study objective

Objective: In this pilot study experience will be obtained in the simultaneous use of PSG, melatonin assay, CBT-measurement and assessment in ICU patients.

### Study design

Study design: Prospective observational study

### Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No known risk is involved in participation. Patients will receive standard intensive care with added non-invasive PSG.

## 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

Non-surgical ICU patients.
Expected duration of ICU-stay > 24 hours.
Written informed consent given by the patient according to the regulations.

## Exclusion criteria

Life expectancy of < 48 hours on ICU admission
Necessity of prolonged deep sedation, > 72 hours
Blindness or severe visual impairment
Known or proven neuropathology
<18 years of age.
Patients who are incapable of giving informed consent

# Study design

## Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 23-07-2012 |
| Enrollment: | 6 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 23-07-2012 |
| Application type: | First submission |
| 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 | NL40705.042.12 |