A qualitative and quantitative evaluation of perioperative sleep

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Aim: The aim of this study is to investigate if and to what extent current clinical perioperative practice disrupts postoperative sleep. Postoperative short-term (one week) and long-term (three months) change in sleep patterns, quality and circadian...

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

Summary

ID

NL-OMON45346

Source
ToetsingOnline

Brief title
Perioperative Sleep

Condition

- Other condition

Synonym
insomnia, sleeping disorder

Health condition

slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anesthesia, perioperative, sleep, surgery

Outcome measures

Primary outcome

Sleep efficiency determined by actigraphy.

Secondary outcome

Subjective sleep measurements and fatigue assessed by questionnaires and other

parameters measured by actigraphy (total sleep time, circadian rhythm).

Study description

Background summary

Sleep is essential to preserve health and is especially important during recovery from illness.[1] Abnormal sleep can aggravate inflammation and pain, can induce mental disorders like delirium and has a substantial effect on mood.[2]-[4]

During the perioperative period a patient is prone to develop sleep problems. Up to 20% of patients who underwent outpatient surgery report the occurrence of sleep problems,[5] in clinically operated patients the rate of sleep problems is up to 23%.[6] Objective measurements show disturbances of the structure of sleep (the *sleep architecture*) in the postoperative period.[7]-[14] These sleep disturbances typically persist until the fourth postoperative day, but may last well up to several weeks.[15]

Perioperative disturbance of sleep is caused by several factors. At least four factors are presumed to have a significant effect on sleep.
1. Anesthesia or the anesthetic drugs could cause a shift in the circadian rhythm, a "jetlag". Hormone secretion, body temperature and sleep-wake timing are, among other things, regulated by the circadian rhythm and disruption can lead to various pathological conditions affecting postoperative recovery.

2. Surgery causes a great amount of physiological stress, with the release of inflammatory proteins and stress hormones.[18] This is known to disrupt normal sleep architecture.[19], [20]
3. The hospital environment with an abundance of night-time light and sound causes a severe fragmentation of sleep and thereby prevents a normal cycling of sleep stages.[21]-[23]
4. The primary illness and its treatment can cause major sleep problems. Many kinds of medication have side effects causing sleep disturbance and pain associated with the primary illness, e.g. hip arthrosis, can cause significant sleep fragmentation.[24]

A reduction of sleep in the perioperative period may lead to an increased risk of complications, a longer length of stay and a delayed return to daily activities or work. Besides their effect on physiology, sleep problems have a strong influence on patient experience and satisfaction. Nevertheless, professionals in clinical medicine have little concern for the quality of sleep during the perioperative process. This reflects a lack of clinical data, fundamental knowledge, and awareness among health care professionals

Study objective

Aim: The aim of this study is to investigate if and to what extent current clinical perioperative practice disrupts postoperative sleep. Postoperative short-term (one week) and long-term (three months) change in sleep patterns, quality and circadian rhythm will be assessed in orthopedic patients. This study is the foundation for future studies, directed at understanding the consequences of sleep disruption for recovery process after surgery. In the future, we would like to test interventions that aim to diminish perioperative sleep disruption and as a result improve the recovery process.

Objectives:
* To quantify a difference in sleep efficiency, quality and fragmentation between preoperative baseline measurements and measurements one week and three months after surgery.
* To create a framework for future studies investigating the consequences of disturbed sleep for recovery after surgery and at investigating interventions to diminish the perioperative disturbance of sleep to improve the recovery process.

Study design

The study is designed as a single-center prospective observational cohort study at the Orthopedic, Traumatology and Anesthesia departments of the Erasmus MC. Measurements will be performed in patients homes and on the orthopedic and traumatology ward. The appropriate amount of patients are expected to be included in nine months.

Study burden and risks

The study is observational in nature and poses no risk to participants. The burden put on participants consists of the following. On three moments in time participants will wear an actigraphy wristband and fill out several short questionnaires over a course of six days. The wristband is waterproof, but can be taken off for showering and will be taken off during surgery. The questionnaires should all together take not more than 10 minutes per day to complete.

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

- Undergoing one of the following procedures under general anaesthesia in the Erasmus MC: elective primary or secondary total hip replacement surgery or total knee replacement surgery, or elective major traumatology surgery of the extremities.
- Anticipated duration of surgery >120 minutes.
- Anticipated duration of postoperative hospitalization > 2 days and < 7 days.
- Be able to understand and write in the Dutch or English language.
- Be 18 years of age or older
- Be able to read, understand and sign the informed consent form.

Exclusion criteria

- Patients undergoing surgery within 8 days of preoperative screening
- Patients (being) admitted more than one day preoperatively
- Patients that have one of the following preoperative conditions:
* Neurological deficits caused by cerebral diseases (vascular or other).
* Use of antipsychotic or sedative medication before inclusion (benzodiazepines, melatonin, antidepressants).
* Use of strong opiates before inclusion.
* Obstructive Sleep Apnea Syndrome (OSAS).
- Patients who have been working night shifts during the past three months.
- Patients admitted to the intensive care unit after surgery, planned or unplanned.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2017
Enrollment:	76
Type:	Anticipated

Ethics review

Approved WMO Date:	23-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59274.078.16